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TITLE: Intervention to Decrease Risk for STDs and Unintended Pregnancies Among Navy Women Aboard Ships: A Biopsychosocial Approach

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13. ABSTRACT (Maximum 200 Words)
Unintended pregnancies (UIPs) and STDs with their sequelae of ectopic pregnancy continue to be epidemic among active duty enlisted women. Such reproductive health problems result in major morbidity among affected women as well as posing a potential threat to combat readiness. UIPs and STDs result from complex interactions between biological and behavioral factors. The ultimate control in preventing such morbidities must rely on both behavioral and biologic strategies. The primary aim of the project is to develop, implement and evaluate an intervention which emphasizes correct information, motivation and behavioral skills building (IMB Model) coupled with non-invasive screening using urine-based amplified DNA techniques to detect C. trachomatis and N. gonorrhoeae and urine-based pregnancy testing. A randomized controlled trial design was employed to evaluate the impact of the intervention on the experimental group using both self-report questionnaires (psychosocial and behavioral risk factors) and results from the STD and pregnancy screening tests as measures. The control intervention consisted of a prevention program focusing on nutrition, breast cancer, fitness and injury prevention. Questionnaires and biologic testing were completed as baseline, 2-4 weeks, 9-12 months post intervention. Participants (N=2157) were women enrolled in recruit training for the U.S. Marine Corps. Results show that the intervention has had a significant impact on decreasing STDs over the study period.

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3. INTRODUCTION

Overall Goal: To prevent sexually transmitted diseases (STDs) and unplanned pregnancies (Focus curriculum) and to promote good nutritional habits and reduce sports/training injuries (Fitness-for-Life curriculum) through the provision of information, communication and problem-solving skills training, use of program-specific videos, and group discussions which emphasize prevention of risk behaviors and negative peer influences. The curricula for both components were implemented in 4, two-hour sessions that occur during Recruit Training (Parris Island, SC). Screening for pregnancy and prevalent STDs, including chlamydia, gonorrhea, and trichomonas is also included.

Participants: Junior, enlisted women Marine Recruits who voluntarily agreed to participate in the program were randomly assigned by platoons to either the Focus (Study condition) or Fitness-for-Life (Control condition) Curricula at arrival at recruit training.

Assessments: *(Completed)* All participants completed a self-report questionnaire of their knowledge, attitudes, beliefs, and behaviors regarding STDs, unplanned pregnancies, nutrition and fitness at T-1 baseline (prior to participation in the Program at Recruit Training Regimen-RTR, Parris Island, SC), at T-2 after completing Marine Combat Training (MCT at Camp LeJeune, NC, approximately 2-4 weeks from graduation from recruit training) which was preceded by boot leave, and at T-3 which is 9-12 months post-MCT at their first duty assignment or MOS School. These individuals were also screened for pregnancy and STDs at each of the three assessment periods.

Program Evaluation: *(Ongoing analyses, see publications to date and plans for future manuscripts)* The primary goal of the program evaluation was to determine the feasibility and effectiveness of the Focus curriculum for preventing unplanned pregnancies and STDs and the Fitness-for-Life curriculum for promoting good nutritional habits and reducing sports/performance injuries in junior enlisted women Marines.

Specific Aims:

(A) Develop, implement, and evaluate a reproductive health educational and cognitive-behavioral skills-building intervention (behavioral intervention) designed to modify knowledge, psychosocial and behavioral risk factors associated with UIPs and STD acquisition.

(B) Test the relevance of the Information, Motivation, and Behavioral Skills (IMB) Model in explaining the determinants of behaviors linked with UIPs and STDs.

(C) Define the prevalence of UIPs and STDs, emphasizing the most common bacterial agents, such as *C. trachomatis* and *N. gonorrhoeae*, and their sequelae of PID and ectopic pregnancy.

(D) Utilize pregnancy and STD diagnostic screening tests as biological markers to validate self-reported behaviors and to evaluate the impact of the behavioral intervention.

(E) Assess the performance of non-invasive, non-culture-base screening tests for the detection of as *C. trachomatis* and *N. gonorrhoeae* by ligase chain reaction (LCR) technique on first void urine compared to standard tests applied to (invasive) endocervical and urethral specimens by the presence or absence of symptoms.

4. BODY

Overview

The research methods, results, and discussion are described below in relation to the Statement of Work for the grant period August 7, 1995-August 6, 2003.
T-1 Period: Completed the basic analysis for the baseline data related to STDs (chlamydia, gonorrhea, trichomonas, bacterial vaginosis, and pregnancy), self-reported questionnaires for T-1), and prepared and submitted and presented abstracts describing the baseline data to scientific meetings.
T-2 Period: Completed the basic analysis for the data for the second data collection period including data related to STDs (chlamydia, gonorrhea, trichomonas, bacterial vaginosis, and pregnancy), self-reported questionnaires for T-2), and prepared and submitted and presented abstracts describing the baseline data to scientific meetings.
T-3 Period: Complete a second follow-up (T-3) on all of the participating women Marines including the self-reported questionnaire and first void urine specimens for *C. trachomatis, N. gonorrhoeae*, and pregnancy screening. Completed data entry and cleaning of data from the questionnaire and for the biologic specimens. Completed the initial analyses for this data set including evaluation of the efficacy of the experimental (*FOCUS*) and control (*Fitness for Life*) intervention programs to prevent STDs and unplanned pregnancies and submitted a manuscript describing the evaluation of the evaluation which is now under review (See **Appendix 1.a.).**

STATEMENT OF WORK (SOW)

The following summarizes progress on the SOW activities:

(A) Select a group of surface destroyer and submarine tender ships to focus initial data collection of which two ships will be targeted as study ships for the current study.

COMPLETED

1. The target population for implementation of the project is US Marine Corps Recruits from the Marine Corps Recruiting Depot (MCRD), Recruit Training Regimen (RTR) on Parris Island, SC. To date, we have approached 2,228 women Marine recruits to participate in the *FOCUS-Fitness for Life* intervention. Of these women 94% voluntarily consented to participate in the program (N=2,157). Of these women, 49% were assigned to the *FOCUS* program and 51% were assigned to the *Fitness for Life* program. The intervention component (T-1) of the program is finished with 1,916 women completing the intervention and graduating from

recruit training (89% of those enrolled); (213) were discharged from Recruit Training.)

2. The Marine Combat Training (MCT) component of data collection (T-2) at Camp LeJeune, NC. At this initial follow-up, the participants were screened for pregnancy and STDs (chlamydia, gonorrhea, trichomonas) and completed a short interim behavioral questionnaire. A total of 1,748 women completed T-2, which represents 81% of those originally enrolled at T-1 (91% of those who completed T-1).

3. A second follow up (T-3) of the participants was completed December 2001 (begun July 1, 2000). We established follow-up sites on Okinawa, Japan (Camp Hansen, Camp Lester and others), in Jacksonville NC (Camp LeJeune, Camp Geiger, and others), and southern California (Camp Pendleton, 29 Palms, San Diego) to reach the women Marine participants who were assigned to duty stations in and around these regions. The women were screened for pregnancy, STDs (chlamydia, gonorrhea, trichomonas), and completed a self-reported behavioral questionnaire. In addition to these locations, MCRD at Parris Island, SC served as the coordinating site to reach women who were stationed in other regions of the country and abroad beyond our formal established research sites. These women completed a second-follow-up questionnaire and not the clinical specimen collections since it was not possible to transport these specimens from so many places adequately. 1,381women were followed at T-3 representing 72% of those who completed the T-1 assessment.

(B) Brief the Commanding Officers (COs) of the target populations.

COMPLETED

We presented the final results and findings to the Marine Command at Parris Island on June 10-11, 2003 (see attached brief, **Appendix 2**).

(C) Conduct elicitation research (focus groups) in order to develop a self-report question to assess knowledge, attitudes, and beliefs, and behaviors of the target population and to develop a military-specific behavioral intervention to reduce risk or UIPs and STDs in the target population, including development, implementation, and evaluation of the intervention. (This includes all of our analyses evaluating the baseline descriptive data, the biologic STD test efficacy evaluations, and the evaluation of the efficacy of the actual cognitive, behavioral and skills building intervention FOCUS compared to FITNESS FOR LIFE). This latter emphasis on analyses has been the focus for the past 12 months.

COMPLETED:

The analysis of the evaluation of the program is completed and a manuscript is submitted and under review (see **Appendix 1.a**.). In addition, evaluation of descriptive

findings from the control intervention (Fitness for Life) regarding fitness and nutrition is ongoing and a manuscript describing these results is under preparation.

1. All program materials, including videos, training exercises, training materials, and evaluation (assessment) instruments were developed.

2. All study participants were enrolled into the *FOCUS-Fitness for Life* intervention program as described above in section A-1 (T-1).

3. MCT follow-up phase (T-2) of the study was completed in January 2001. This phase includes 1,748 women as described in section A-2 above.

4. The second follow-up (T-3) of the study was completed in December 2001 as described above in sections A-3 above.

The initial analyses from baseline data from T-1 is described in the first published article and abstracts: Boyer, Shafer, Shaffer et al. Submitted 2003, **Appendix 1.a.**; Shafer, Moncada, Boyer et al. *Journal of Clinical Microbiology*, 41(9):4395-99, 2003, **Appendix 1.b.**; Yen, Shafer, Moncada et al. *Obstetrics and Gynecology*. In Press, 2003, **Appendix 1.c.**; Boyer, Shafer, Moncada et al. ISSTDR: *Sexually Transmitted Infections* 241-246, 2001, **Appendix 1.d.**; Shafer, Boyer, Pang, et al. European Chlamydia Congress, Helsinki, Finland, 2000, **Appendix 3.a.**; Boyer and Shafer, *Journal of Adolescent Health*, 30:129, 2002, **Appendix 3.d**. Yen, Shafer, Moncada et al., *Journal of Adolescent Health*, 30(2):97-98, 2002.**Appendix 3.e.**; Boyer and Shafer, *Journal of Adolescent Health*, 32:129, 2003. **Appendix 3.f.** Yen, Shafer, Moncada et al., *Journal of Adolescent Health*, 32:128, 2003.**Appendix 3.g.**

(D) Review STD logs and clinical records to establish the prevalence of reproductive health outcomes in the target population.

COMPLETED

1. All activities related to this task were completed prior to this fiscal year.

2. We determined the baseline prevalence for *C. trachomatis*, *N. gonorrhoeae*, and *T. vaginalis* in the target population We found an overall 13% rate of STD infections among entering Marine recruits including 11% infected with chlamydia, 2% with gonorrhea and 2% with trichomonas. (See Shafer, Boyer, Pang, et al. European Chlamydia Congress, Helsinki, Finland, 2000, **Appendix 3.a.)**

3. We determined that using Nugent's gram stain technique is a feasible method for use in a military setting and is able to determine accurately the presence of bacterial vaginosis (BV) which we found to be present in 27% (28% sexually active and 18% never sexually active, p=.001). of recruits had BV. BV determined by Nugent's criteria was significantly related to : race/ethnicity (p=.001); self reported vaginal discharge (p=.001) and odor (p<.01); current chlamydial infection

(p<.01); and inversely related to hormonal contraceptive use (p=.013). (Yen, Shafer, Moncada et al, *Obstetrics Gynecology, In Press 2003,* **Appendix 1.c.);** Shafer, Boyer, Schachter , et al., Presented at the 2003 ISSTDR Congress, Ottawa, Canada, 2003, **Appendix 3.i. and 4.b.)**.

(E) Test the feasibility of non-invasive STD screening tests (urine) for chlamydia and gonorrhea in comparison to standard invasive tests.(Shafer, Moncada, Boyer CB, et al., *Journal of Clinical Microbiology*, 41(9):4395-99, 2003, **Appendix 1.b.)**.

1. All activities related to this task were completed prior to this fiscal year.

   We also determined the performance profiles for the 3 different collection methods to detect *C. trachomatis* and *N. gonorrhoeae* by nucleic acid amplification tests applied to endocervical, first catch urine, and self-administered vaginal swab specimens. (See Shafer, Boyer, Pang, et al. European Chlamydia Congress, Helsinki, Finland, 2000, **Appendix 3.a.** and Shafer, Moncada, Boyer CB, et al., *Journal of Clinical Microbiology* 41(9):4395-99, 2003, **Appendix 1.b.)**.

2. In addition, we evaluated the efficacy of applying the Nugent's gram stain technique to the diagnosis of bacterial vaginosis (BV) and compared results with results from a pH test card and the Papanicolaou smear. This paper was an oral presentation presented at the annual meeting of the Society of Adolescent Medicine by a fellow of Drs. Shafer and Boyer (Dr. Yen) in March 2003 (Yen, Shafer, Moncada et al, *Journal of Adolescent Health*, 2002, **Appendix 3.g.** and Yen, Shafer, Moncada et al. *Obstetrics Gynecology*. Accepted 2003, **Appendix 1.c.)**

(F) Test the acceptability of screening for pregnancy in the target population.

COMPLETED

5. KEY RESEARCH ACCOMPLISHMENTS TO DATE

(A) Designed and successfully implemented an intense 8 hour training program within a complex recruit training schedule to decrease STDs and unplanned pregnancies.

(B) Showed the feasibility of implementing an intense cognitive-behavioral intervention to decrease STDs and unplanned pregnancies in the military setting.

(C) Showed the feasibility of implementing a universal STD and pregnancy screening program using multiple collections over time within the military setting.

(D) Determined the feasibility of following individual participants over 3 different time periods during their first enlistment tour.

(E) Described basic reproductive health behaviors including sexual activity, sexual partner information, contraceptive use, and other behavioral risk factors.

(F) Determined the prevalence rates for common STDs among Marine women recruits: *C. trachomatis (11%), N. gonorrhoeae (2%), and T. vaginalis (2%).*

(G) Evaluated the performance profiles of three different techniques for collecting STD specimens (endocervical, first part urine and self-administered vaginal swabs) and determined that vaginal or a combination of endocervical and vaginal detect the most infections and showed that the self-administered vaginal swabs had the highest performance for identifying chlamydia compared to the endocervix and urine specimens.

(H) Determined that self-administered vaginal swabs are acceptable to this population of young women.

(I) Determined that 92% of the Papanicolaou smears were entirely normal and 8% had evidence of HPV (human papillomavirus infection) with no cancer identified.

(J) Determined BV to be present in 27% (28% sexually active and 18% never sexually active, p=.001) of recruits and BV was significantly related to : race/ethnicity, self reported vaginal discharge and odor, current chlamydial infection, and inversely related to hormonal contraceptive use. (Yen, Shafer, Moncada et al, *Obstetrics Gynecology, In Press 2003,* **Appendix 1.c.**; Shafer, Boyer, Schachter , et al., Presented at the 2003 ISSTDR Congress, Ottawa, Canada, 2003, **Appendix 3.i. and 4.b.**). Age, partner's race at last sex, perception that sexual partners had other partners, birth control use and STD related symptoms at baseline screening were associated with a STD diagnosis at baseline analyzing the data using logistic regression techniques.

(K) Determined that the cognitive behavioral intervention to prevent STIs and Ups and their associated risk behaviors in a group randomized controlled trial was successful. We found that a significantly higher proportion of the control intervention group (23.9%) than the experimental intervention group (17.9%) tested positive for a post-intervention STI or UP (Odds Ratio (OR) =1.41, 95% Confidence Interval (CI) =1.01-1.98). Among participants who had no pre-intervention history of STIs or pregnancy, but who engaged in risky sexual behaviors just prior to recruit training entry, the control intervention group (21.8%) was significantly more likely than the experimental intervention group (8.0%) to acquire a post-intervention STI (OR=3.24, CI=1.74-6.03). Among participants who reported not being sexually experienced at the baseline assessment, control intervention participants were significantly more likely than experimental intervention participants to report having multiple sexual partners (OR=1.87, 95% CI=1.01-3.47) and casual sexual partners (OR=2.05, 95% CI=1.04-4.08) during the post-intervention period. (See manuscript submitted for publication, **Appendix 1.a.).**

6. REPORTABLE OUTCOMES

(A) Developed and produced a complete manual describing "how to" implement the FOCUS/FITNESS FOR LIFE interventions.

(B) Produced a skills building teaching video entitled, "GOOD TO GO" as a part of this project, which is being used in the intervention training.

(C) Developed a computerized and manual system for tracking recruits throughout their first enlistment.

(D) Assisted the 4th Battalion, at the Marine Corps Recruiting Depot, Parris Island, SC to adopt and implement portions of the FOCUS intervention into their overall recruit training for women Marines.

(E) Publications and presentations during project period

1. Boyer CB, Shafer MA, Shaffer RA, Brodine SK, Pollack LM, Betsinger K, Chang Y, Kraft HS, Schachter J. A Cognitive-Behavioral Intervention to Prevent Sexually Transmitted Infections and Unintended Pregnancies in a National Sample of Women Entering Recruit Training for the Military: Evaluation of a Group Randomized Controlled Trial. Submitted 2003. **(Appendix 1.a.)**

2. Shafer MA, Moncada J, Boyer CB, Betsinger K, Flinn SD, Schachter J. Comparing the FVU, Self-collected Vaginal Swabs and Endocervical Specimens to Detect *C. trachomatis* and *N. gonorrhoeae* using Nucleic Acid Amplification Tests. *Journal of Clinical Microbiology,* 41(9):4395-99, 2003. **(Appendix 1.b.)**

3. Yen S, Shafer MA, Moncada J, Campbell CJ, Flinn SD, Boyer CB. Prevalence and Clinical Correlates of Bacterial Vaginosis among Sexually Experienced and Non-Sexually Experienced Young Women Entering The Military. *Obstetrics and Gynecology.* In Press 2003. **(Appendix 1.c.)**

4. Shafer MA, Boyer CB, Schachter J, Moncada J, Pollack LM, Chang Y, Shaffer RA. Predicting Acquisition of *C.Trachomatis*, *N.Gonorrhoeae*, and *T.Vaginalis* in a Non-Clinical National Sample of Young Military Women During Their First Year of Service. Presented at the 2003 ISSTDR Congress, Ottawa, Canada, July 27-30, 2003. **(Appendix 3.i.)**

5. Boyer CB, Shafer MA, Schachter J, Shaffer RA, Pollack LM, Chang Y, Brodine S. Preventing STDs and Unplanned Pregnancy in a National, Non-Clinical Sample of Young Women: A Cognitive-Behavioral, Group, Randomized Controlled Intervention Trial For Military Recruits. Presented at the 2003 ISSTDR Congress, Ottawa, Canada, July 27-30, 2003. **(Appendix 3.h.)**

6. Boyer CB, Shafer MA. Preventing STDs and Unplanned Pregnancies: A Cognitive-Behavioral Intervention for Young Women Entering the Military. *Journal of Adolescent Health*, 32(2):129, 2003. **(Appendix 3.f.)**

7. Yen S, Shafer MA, Moncada J, Boyer, CB. Prevalence Of Bacterial Vaginosis by Nugent's Criteria in a Non-Clinic Sample of Young Women Entering the Military: Relationships with Sexual Experience, Vaginal Symptoms and Signs. *Journal of Adolescent Health*, 32(2):128, 2003. **(Appendix 3.g.)**

8. Yen S, Shafer MA, Moncada J, Campbell HC, Henry LC, Flinn K, Flinn S, Boyer CB. How Common is Bacterial Vaginosis (BV) and How Good are the Tests: Comparing FemExam (R) PH, Amine Testcard and Papanicolaou Smear to Nugent's Criteria in a Non-clinic Population of Young Female Military Recruits. *Journal of Adolescent Health*, 30(2): 97-98, 2002. **(Appendix 3.e.)**

9. Boyer CB, Shafer MA. Development of a Cognitive-Behavioral Group Randomized Control Intervention Trial to Prevent STDs and Unplanned Pregnancies for Young Women Entering the US Military. *Journal of Adolescent Health,* 30(2):129, 2002.. **(Appendix 3.d.)**

10. Boyer CB, Shafer MA, Betsinger K, Shaffer RA, Brodine SK, Kraft H, Schachter J: Preventing HIV, STDs, and Unplanned Pregnancies in Young Women Entering the US Military: A Cognitive-Behavioral Approach. 2001 National HIV Prevention Conference, Atlanta, Georgia, August 12-15, 2001. **(Appendix 3.c.)**

11. Boyer CB, Shafer MA, Moncada J, Schachter J, Shaffer RA, Brodine SK: Sociodemographic, Behavioral, and Clinical Factors Associated with STDs in a National Sample of Women Entering the US Military. *ISSTDR: Sexually Transmitted Infections* 241-246, 2001. **(Appendix 1.d.)**

12. Boyer CB, Shafer MA, Pollack L, Kraft H. Sexually Transmitted Disease Acquisition in a National, Non-Clinical, Diverse Sample of Young Women: Associations of Sociodemographic, Behavioral, and Clinical Factors. Proceedings of The Society of Behavioral Medicine's 22nd Annual Meeting, Seattle, Washington, March 21-24, 2001. **(Appendix 3.b.)**

13. Shafer MA, Boyer CB, Pang F, Moncada J, Dubovtsev A, Brodine S, Shaffer R, Schachter J. Comparison of 3 Specimen Collection Techniques – Endocervical and Self-administered Vaginal Swab to Screen for *C. trachomatis* (CT) and *N. gonorrhoeae* (GC) by NAATS in Women Marine Recruits. IV European Chlamydia Congress, Chlamydia 2000, Helsinki, Finland, August 2000. **(Appendix 3.a.)**

(F) In Preparation

1. Shafer MA, Boyer CB, Schachter J, Moncada J, Pollack LM, Chang Y, Shaffer RA, Brodine S. Predicting Acquisition of *C.Trachomatis*, *N.Gonorrhoeae*, and *T.Vaginalis* In a Non-Clinical National Sample Of Young Military Women During Their First Year Of Service. In Preparation, 2003. **(Appendix 4.b.)**

2. Boyer CB, Shafer MA, Schachter J, Shaffer R, Brodine S, Canchola C, Pollack L. Sociodemographic, Behavioral and Clinical Factors Associated with STDs in a National Sample of Women Entering the US Military. In Preparation, 2003.

3. Boyer CB. Shafer MA. Pollack L, Kraft H. Predicting Sexual Risk, STD History, and Acquisition of STDs Using the Information, Motivation, and Behavioral Skills (IMB) Model. In Preparation, 2003.

4. Garber AK, Boyer CB, Pollack, Chang YJ, and Shafer MA: Factors Associated with Weight Dissatisfaction in Female Military Recruits. In Preparation, 2003.

5. Shafer MA, Boyer CB, Betsinger K, Schachter J. Are Routine Pelvic Exams Necessary Annually in Healthy Sexually Active Young Adults? STD screening and Papanicolau smears in military recruits—an "ideal" national sample. In Preparation, 2003.

6. Boyer CB, Shafer MA, Pollack LM. Evaluating the Intervention to Prevent Unplanned Pregnancies and Sexually Transmitted Diseases Using the Informational, Motivational and Behavioral Skills Model (IMB).In Preparation, 2003.

7. CONCLUSIONS TO DATE:

(A) Implementation of an intense cognitive-behavioral intervention to decrease acquisition of STDs and unplanned pregnancy is feasible within a military setting.

(B) Implementation of a universal STD and pregnancy screening program is feasible within a military setting over time.

(C) Asymptomatic and undetected STDs especially *C. trachomatis* are epidemic among young women entering the U.S. Marines.

(D) Acquisition of STDs during the first year of military service after graduation from recruit training is very high (24%).

(E) Young women Marines are placing themselves at risk for acquisition of STDs and unplanned pregnancy by engaging in risky sexual behaviors including having unprotected sexual intercourse, having sexual intercourse with multiple partners, among other risky behaviors.

(F) It is critical to develop an annual universal STD screening program for STDs to be implemented immediately among young military women because of the high rates of STD acquisition.

(G) Findings of high rates of STDs and risky behaviors linked to STD acquisition and unplanned pregnancy dictate that the implementation of an STD unplanned planned pregnancy prevention program for young women Marines is essential to support combat readiness.

(H) Female military recruits report a high degree of weight dissatisfaction despite normal body mass index measures (BMIs). Body dissatisfaction was significantly related to nine factors using regression analysis: BMI, history of dieting practices, intention to diet to make weight, history of weight fluctuation, inadequacy of current diet, disparity between highest and lowest adult weight, perceived acceptability of fasting, intention to crash diet, and fitness knowledge Although weight limits are needed to maintain performance standards in the military, it should be recognized that weight dissatisfaction is prevalent among women in the Marines and is associated with unhealthy dieting behaviors.

(I) The cognitive behavioral intervention successfully decreased reproductive morbidity such as acquisition of STDs especially among specific subgroups of at risk young women during their first year of active duty. A significantly higher proportion of the control intervention group (23.9%) than the experimental intervention group (17.9%) tested positive for a post-intervention STI or UP (Odds Ratio (OR) =1.41, 95% Confidence Interval (CI) =1.01-1.98). Among participants who had no pre-intervention history of STIs or pregnancy, but who engaged in risky sexual behaviors just prior to recruit training entry, the control intervention group (21.8%) was significantly more likely than the experimental intervention group (8.0%) to acquire a post-intervention STI (OR=3.24, CI=1.74-6.03). Among participants who reported not being sexually experienced at the baseline assessment, control intervention participants were significantly more likely than experimental intervention participants to report having multiple sexual partners (OR=1.87, 95% CI=1.01-3.47) and casual sexual partners (OR=2.05, 95% CI=1.04-4.08) during the post-intervention period. The findings of this randomized controlled trial indicate that use of cognitive-behavioral interventions is an effective strategy to reduce behavioral risk and prevent STIs and UPs in young sexually active women who are not seeking health care.

8. References:

1. Publications (articles)

1. Boyer CB, Shafer MA, Moncada J, Schachter J, Shaffer RA, Brodine SK: Sociodemographic, Behavioral, and Clinical Factors Associated with STDs in a National Sample of Women Entering the US Military. *ISSTDR: Sexually Transmitted Infections* 241-246, 2001 **(Appendix 1.d.)**

2. Boyer CB, Shafer MA, Shaffer RA, Brodine SK, Pollack LM, Betsinger K, Chang Y, Kraft HS, Schachter J. A Cognitive-Behavioral Intervention to Prevent Sexually Transmitted Infections and Unintended Pregnancies in a National Sample of Women Entering Recruit Training for the Military: Evaluation of a Group Randomized Controlled Trial. Submitted 2003. **(Appendix 1.a.)**

3. Garber AK, Boyer CB, Pollack, Chang YJ, and Shafer MA: Factors Associated with Weight Dissatisfaction in Female Military Recruits. Manuscript In Preparation, 2003.

4. Shafer MA, Boyer CB, Schachter J, Moncada J, Pollack LM, Chang Y, Shaffer RA, Brodine S. Predicting Acquisition Of *C. trachomatis*, *N. gonorrhoeae*, and *T.Vaginalis* In a Non-Clinical National Sample of Young Military Women During Their First Year of Service. Manuscript in Preparation 2003.

5. Shafer MA, Moncada J, Boyer CB, Betsinger K, Flinn SD, Schachter J. Comparing the FVU, Self-collected Vaginal Swabs and Endocervical Specimens to Detect *C. trachomatis* and *N. gonorrhoeae* using Nucleic Acid Amplification Tests. *Journal of Clinical Microbiology* 41(9):4395-99, 2003.. **(Appendix 1.b.)**

6. Yen S, Shafer MA, Moncada J, Campbell CJ, Flinn SD, Boyer CB. Prevalence and Clinical Correlates of Bacterial Vaginosis among Sexually Experienced and Non-Sexually Experienced Young Women Entering The Military. *Obstetrics and Gynecology*. In Press 2003. **(Appendix 1.c.)**

2. Abstracts of Research Presentations:

1. Shafer MA, Boyer CB, Pang F, Moncada J, Dubovtsev A, Brodine S, Shaffer R, Schachter J. Comparison of 3 Specimen Collection Techniques – Endocervical and Self-administered Vaginal Swab to Screen for *C. trachomatis* (CT) and *N. gonorrhoeae* (GC) by NAATS in Women Marine Recruits. IV European Chlamydia Congress, Chlamydia 2000, Helsinki, Finland, August 2000.**(Appendix 3.a.)**

2. Boyer CB, Shafer MA, Pollack L, Kraft H. Sexually Transmitted Disease Acquisition in a National, Non-Clinical, Diverse Sample of Young Women: Associations of Sociodemographic, Behavioral, and Clinical Factors. Proceedings of The Society of Behavioral Medicine's 22nd Annual Meeting, Seattle, Washington, March 21-24, 2001. **(Appendix 3.b.)**

3. Boyer CB, Shafer MA, Betsinger K, Shaffer RA, Brodine SK, Kraft H, Schachter J: Preventing HIV, STDs, and Unplanned Pregnancies in Young Women Entering the US Military: A Cognitive-Behavioral Approach. 2001 National HIV Prevention Conference, Atlanta, Georgia, August 12-15, 2001. **(Appendix 3.c.)**

4. Boyer CB, Shafer MA: Development of a Cognitive-behavioral Group Randomized Control Intervention Trial to Prevent STDs and Unplanned Pregnancies for Young Women Entering the US Military. *Journal of Adolescent Health*, 30(2):129, 2002. **(Appendix 3.d.)**

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9. Boyer CB, Shafer MA, Schachter J, Shaffer RA, Pollack LM, Chang Y, Brodine S. Preventing STDs and Unplanned Pregnancy in a National, Non-Clinical Sample of Young Women: A Cognitive-Behavioral, Group, Randomized Controlled Intervention Trial For Military Recruits. Presented at the 2003 ISSTDR Congress, Ottawa, Canada, July 27-30, 2003. **(Appendix 3.h.)**

10. Shafer MA, Boyer CB, Schachter J, Moncada J, Pollack LM, Chang Y, Shaffer RA. Predicting Acquisition of *C. Trachomatis*, *N. Gonorrhoeae*, and *T. Vaginalis* in a Non-Clinical National Sample of Young Military Women During Their First Year of Service. Presented at the 2003 ISSTDR Congress, Ottawa, Canada, July 27-30, 2003. **(Appendix 3.i.)**

Appendices

1. Articles

2. Brief, June 2003, Presented to Lt. Colonel Johnson and Colonel Bearor, at Marine Corps Recruiting Depot, Parris Island, SC.

3. Abstracts

4. Presentations

Appendix 1.

Articles

a. Boyer CB, Shafer MA, Shaffer RA, Brodine SK, Pollack LM, Betsinger K, Chang Y, Kraft HS, Schachter J. A Cognitive-Behavioral Intervention to Prevent Sexually Transmitted Infections and Unintended Pregnancies in a National Sample of Women Entering Recruit Training for the Military: Evaluation of a Group Randomized Controlled Trial. Submitted 2003.

b. Shafer MA, Moncada J, Boyer CB, Betsinger K, Flinn SD, Schachter J. Comparing the FVU, Self-collected Vaginal Swabs and Endocervical Specimens to Detect *C. trachomatis* and *N. gonorrhoeae* using Nucleic Acid Amplification Tests. *Journal of Clinical Microbiology*, 41(9):4395-99, 2003.

c. Yen S, Shafer MA, Moncada J, Campbell CJ, Flinn SD, Boyer CB. Prevalence and Clinical Correlates of Bacterial Vaginosis among Sexually Experienced and Non-Sexually Experienced Young Women Entering The Military. Obstetrics and Gynecology. In Press, 2003.

d. Boyer CB, Shafer MA, Moncada J, Schachter J, Shaffer RA, Brodine SK: Sociodemographic, behavioral, and clinical factors associated with STDs in a national sample of women entering the US military. *ISSTDR: Sexually Transmitted Infections* 241-246, 2001.

Appendix 1.a.

Boyer CB, Shafer MA, Shaffer RA, Brodine SK, Pollack LM, Betsinger K, Chang Y, Kraft HS, Schachter J. A Cognitive-Behavioral Intervention to Prevent Sexually Transmitted Infections and Unintended Pregnancies in a National Sample of Women Entering Recruit Training for the Military: Evaluation of a Group Randomized Controlled Trial. Submitted 2003.

A Cognitive-Behavioral Intervention to Prevent Sexually Transmitted Infections and Unintended Pregnancies in a National Sample of Women Entering Recruit Training for the Military: Evaluation of a Group Randomized Controlled Trial

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ABSTRACT

Context.-Few cognitive-behavioral interventions have focused on prevention of sexually transmitted infections (STIs) and unintended pregnancies (UPs) in healthy, sexually active women in a single study.

Objective.-To evaluate the effectiveness of a cognitive-behavioral intervention to prevent STIs and UPs and their associated risk behaviors.

Setting.-The United States Marine Corps recruit training depot.

Design.-A group randomized controlled trial with two follow-up assessments.

Participants.-All Marine Corps female recruits in training between June 1999 and June 2000.

Intervention.-Based on the Information, Motivation, and Behavior, and Behavioral Skills Model (IMB), the intervention's goals were to: increase knowledge to prevent STIs and UPs; build decision-making and communication skills; identify and modify risk factors; and build skills to seek reproductive health care.

Main Outcome Measures.-Laboratory verified *Chlamydia trachomatis, Neisseria gonorrhoeae*, *Trichomonas vaginalis* and pregnancy, and self-reports of multiple and casual sexual partners, and inconsistent condom use

Results.-A significantly higher proportion of the control intervention group (23.9%) than the experimental intervention group (17.9%) tested positive for a post-intervention STI or UP (Odds Ratio (OR) =1.41, 95% Confidence Interval (CI) =1.01-1.98). Among participants who had no pre-intervention history of STIs or pregnancy, but who engaged in risky sexual behaviors just prior to recruit training entry, the control intervention group (21.8%) was significantly more likely than the experimental intervention group (8.0%) to acquire a post-intervention STI (OR=3.24, CI=1.74-6.03). Among participants who reported not being sexually experienced at the baseline assessment, control intervention participants were significantly more likely than

experimental intervention participants to report having multiple sexual partners (OR=1.87, 95% CI=1.01-3.47) and casual sexual partners (OR=2.05, 95% CI=1.04-4.08) during the post-intervention period.

Conclusions.-The findings of this randomized controlled trial indicate that use of cognitive-behavioral interventions is an effective strategy to reduce behavioral risk and prevent STIs and UPs in young sexually active women who are not seeking health care.

INTRODUCTION

Background

Sexually transmitted infections (STIs) are epidemic among sexually experienced adolescents and young adults, ages 15-24 years. Of the estimated 15 million new STI cases diagnosed annually in the United States, adolescents comprise one-fourth of the cases.[1] Women, by far, share the largest burden of STIs, suffering more frequent and serious complications than men. An estimated 20% of women diagnosed with *Chlamydia trachomatis and Neisseria gonorrhoeae* also experience pelvic inflammatory disease (PID) which can lead to chronic pelvic pain, infertility, and potentially fatal ectopic pregnancy.[2, 3] Further, *Chlamydia trachomatis, Neisseria gonorrhoeae*, and *Trichomonas vaginalis* have been shown to increase the risk of transmitting the Human Immunodeficiency Virus (HIV).[4-6] Although adolescents and young adults (ages 15-24) have a low prevalence of AIDS (<1% of the total cases),[7] it is likely that reducing the high prevalence of STIs in young, sexually experienced women will help to maintain a low HIV infection prevalence in this age group and will reduce high rates in older age groups. Reducing the high prevalence of STIs will also moderate the effects of adverse reproductive health outcomes in women.

As with the larger civilian population, high rates of STIs have been reported among United States active duty military personnel and recruits.[8-11] One study that screened for STIs in male and female soldiers at a large military installation found high rates of *Chlamydia trachomatis* (15.6%) and *Neisseria gonorrhoeae* (7.4%).[8] A study examining the annual incidence of both *Chlamydia trachomatis* and *Neisseria gonorrhoeae* between 1985 and 1996 revealed that the incidences of STIs were three-fold to six-fold higher among male and female active duty Army personnel than among civilian populations.[9] Another study screening for *Chlamydia trachomatis* specifically among female Army recruits between January 1996 and December 1997 identified a

prevalence of 9.2%, with the highest prevalence (12.2%) documented among the 17-year old recruits.[11]

Unintended pregnancies (UPs) are also prevalent among women in the United States. Data compiled from both the National Survey of Family Growth and the Alan Guttmacher Institute, concluding in 1994, indicate that 49% of all pregnancies among adolescent and adult women ages 15-44 in the United Sates were unintended.[12] Incidence data from the United Sates military reveal that although pregnancy rates are comparable to that found among civilians,[13, 14] data on unintended pregnancy rates among active duty junior enlisted personnel were higher (61%) than rates found among civilians,[15] with another study showing even higher rates (82%) among adolescent-aged enlistees.[16]

Research conducted by our group to assess the correlates of UPs among active duty Navy personnel found that UPs were significantly associated with younger age, single marital status, having new or multiple sexual partnerships, and frequent use of condoms.[13] A study of women in the Army found that teen-aged active duty personnel were more likely than their older counterparts to report more lifetime sexual partners, greater frequency of sexual intercourse, lower knowledge levels regarding the female reproductive cycle, and more inconsistent use of contraception.[17] Taken together, these data suggest that many young people join the military with a history of exposure to STIs and risky sexual practices and that this pattern continues during early military service.

Research has shown that STI and HIV prevention interventions based on principles of cognitive-behavioral theory and which target antecedents to STIs are effective strategies for reducing STIs,[18, 19] building skills, and modifying behaviors associated with STIs in heterosexual adolescents and young adults.[20-30] However, none of these studies focused on STIs and UPs simultaneously in a single study. Military recruit training with follow-up during the first year of

military service provides a well-defined, national, non-clinic sample of healthy young women in which to evaluate the effectiveness of a cognitive-behavioral intervention to prevent both STI and UPs. This study reports the evaluation of such an intervention designed to reach this population.

METHODS

Study Enrollment

With approval of the institutional review boards (IRB) for the University of California, San Francisco and the Naval Hospital Beaufort, Beaufort, SC, all United States Marine Corps female recruits were approached by two trained civilian research assistants to voluntarily participate in either a cognitive-behavioral intervention to prevent STIs or UPs (experimental intervention) or an intervention focused on preventing physical training injuries and cancer (control intervention) during the first week of the 13-week recruit training period without military personnel present. Those agreeing to participate in the study signed written informed consent statements and were given the Human Subjects Bill of Rights statement in accordance with IRB guidelines.

Study Design and Procedures

A group randomized controlled trial was used to evaluate the effectiveness of the experimental intervention. During each 13-week recruit training cycle, two platoons (groups of 50-75 women) are formed for training purposes. Platoons are designated by the training command as "lead" and "follow" platoons. Using this natural occurring grouping, "lead" and "follow" platoons were randomly assigned to the experimental intervention group using a computer-generated random number's table that was established prior to the start of the study. Platoons were informed of their group assignment at the first intervention session, after study enrollment and administration of the baseline assessment.

Both experimental and control interventions consisted of four, two-hour, group sessions that took place in weeks 1, 2, 4, and 12 of the 13-week recruit training period. Each session was facilitated by two trained civilian research assistants with groups of 20-25 recruits for the experimental intervention and the entire platoon for the control intervention.

Prior to implementation of the interventions, participants completed a baseline self-administered questionnaire and were screened for *Chlamydia trachomatis, Neisseria gonorrhoeae*, and *Trichomonas vaginalis*. Two post-intervention assessments consisting of self-administered questionnaires and screening for *Chlamydia trachomatis, Neisseria gonorrhoeae*, *Trichomonas vaginalis* and UP were conducted, on average, one month after graduation from recruit training (median =34.5 days, range=11-146 days) and, again on average, 14 months (median =12.8 months, range=6.2-31.7 months) after the baseline assessment. The first follow-up assessment took place after the participants had post-graduation leave (vacation) at the end of a three-week follow-on training period, and the second follow-up assessment took place during the participants' first duty assignment period. Based on prior tracking data of Marines, approximately half of all female Marines are stationed in regions of southern California, eastern North Carolina, and southern Japan during their first year of military service. Given limited resources and the need to have biological specimens collected, stored, and transported, our team decided, a priori, to administer questionnaires and conduct biological screenings only in the three key regions for the second follow-up assessment. For study participants who were not stationed in the three key regions, questionnaires only were sent and returned via U.S. mail. Figure 1 provides an overview of the randomization and the participants' progress through the intervention trial.

Goals of the Interventions

Experimental Intervention

The experimental intervention used a cognitive-behavioral approach, which focused on key elements of the Information, Motivation, Behavioral Skills Model (IMB).[31, 32] The IMB posits that information, motivation, and behavioral skills are the primary determinants of AIDS-preventive behavior, that is information regarding the transmission and prevention of AIDS is a necessary prerequisite of risk-reduction behavior. Motivation to change risk behaviors is a determinant of prevention and affects whether one acts on one's knowledge regarding the transmission and prevention of AIDS. The IMB also asserts that motivation to engage in preventive behaviors is a function of one's attitudes toward the behavior and of perceived norms regarding preventive behaviors. Finally, behavioral skills for engaging in specific preventive behaviors are a third determinant of AIDS-preventive behaviors and affect whether even a knowledgeable, highly motivated person will be able to change his or her behavior to prevent negative health outcomes. Requisite skills to engage in preventive behaviors include the ability to effectively communicate with one's sexual partner about safer sex, to refuse to engage in unsafe sexual practices, and to properly use condoms. For purposes of this study the IMB model was applied to STIs and UPs since these health outcomes are prevalent in young, sexually active women.[3, 12]

The experimental intervention used a variety of educational strategies, including didactic teaching, interactive group discussions and exercises, a self-risk appraisal, and videos (two military-specific videos developed by our group and a video on the basics of a gynecological examination). Figure 2 describes the experimental intervention's overall goals and specific educational objectives.

Control Intervention

The control intervention was identical to experimental intervention with regards to educational strategies, but was designed to: (1) improve participants' physical performance through healthier food choices; (2) reduce participants' risk of sports/physical training injuries; and (3) examine the risk and prevention of cervical and breast cancer in young women.

Incentives

Participants received no incentives for participating in the intervention or the first follow-up assessment, but received a $5.00 phone card or a small gift bag containing cosmetics as a small token for completing the second follow-up assessment.

Primary Outcomes

The primary outcomes of interests were laboratory-verified *Chlamydia trachomatis, Neisseria gonorrhoeae*, *Trichomonas vaginalis* and UPs. At baseline, specimens to test for *Chlamydia trachomatis, Neisseria gonorrhoeae*, and *Trichomonas vaginalis* were obtained during a reproductive health examination required of all female Marines Corps recruits at the beginning of recruit training. The examination included a pelvic examination during which endocervical specimens, first void urine samples, and self-administered vaginal swabs were obtained to test for *Chlamydia trachomatis and Neisseria gonorrhoeae*. Endocervical specimens were transported routinely to the Naval Hospital laboratory for processing within six hours of collection while maintaining the cold chain. The first void urine samples and self-administered vaginal swabs for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* were frozen to -70°C within 24 hours of collection and transported to our university-based research laboratory while maintaining the cold chain. The endocervical, vaginal and first void urine samples for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* were processed using LCx™ in accordance with manufacturer's guidelines.[33]

A second self-administered vaginal swab for *Trichomonas vaginalis* was immediately inoculated, on collection site, into the In-Pouch TV™ (Biomed Diagnostics Laboratories, San Jose, CA) according to the manufacturer's instructions were incubated in pouches immediately after collection at 37°C and were read by trained research assistants for the presence of *Trichomonas vaginalis* at two and five days after inoculation. The same procedures used at baseline for collection and processing of the first void urine and self-administered vaginal swabs specimens were used at both follow-up assessments; however, endocervical specimens were obtainable only at baseline during the routine entry pelvic examination.

All females are screened for pregnancy at recruit training entry, thus baseline pregnancy screening was unnecessary. However, the participants' pregnancy status at both follow-up assessments was ascertained by one of two rapid diagnostic hCG tests applied to urine, the OSOM (One Step One Minute; Wyntek Diagnostics, San Diego, CA) or the Signify hCG Dipstick test (Genzyme, Cambridge, MA). A UP was determined by a single question posed to women identified as having a positive hCG test, "Was this pregnancy planned or unplanned?"

The primary outcome was a composite measure of a post-intervention STI or UP (any post-intervention biological outcome) and single measures of post-intervention STIs and UPs. A post-intervention STI was defined as a positive test (from first void urine or vaginal swab specimens) for any STI (*Chlamydia trachomatis*, *Neisseria gonorrhoeae*, *Trichomonas vaginalis*) at one or both follow-up assessments. A post-intervention UP was defined as a positive hCG test at one or both follow-up assessments among participants who indicated that their pregnancy was unplanned.

Secondary Outcomes

Self-administered questionnaires assessed sociodemographic risk markers and behavioral risk factors associated with acquisition of STIs and UPs, and clinical risk factors. The

sociodemographic risk markers included the study participants' age, race or ethnicity, marital status, and geographic location of residence (metropolitan vs. non-metropolitan as defined by the United States Department of Agriculture for the 1990 Census and based on respondent's home zip code). Lifetime sexual risk factors included the participants' lifetime number of sexual partners, lifetime number of casual sexual partners, frequency of condom use, and frequency of contraception use. Study participants' sexual risk in the three-month period prior to entry into recruit training included the total number of sexual partners, the number of casual partners, frequency of condom use, and frequency of sexual intercourse under the influence of alcohol and other substances. Questions on alcohol and other substance use covered the month prior to recruit training entry. Clinical risk factors included the participants' self-reported history of pregnancy and STIs.

Secondary outcomes included three post-intervention behavioral variables: (1) Multiple Sexual Partners; (2) Casual Sexual Partners; and (3) Inconsistent Condom Use. These variables were measured in the self-administered questionnaire at the second follow-up assessment and covered the entire post-intervention period.

Sample Size

The sample size was originally set at 477 participants per group on the basis of decreasing STIs from 12% at baseline to 6% post-intervention with a power of 0.90. In taking into account the clustering effects of platoons, assuming a within-group correlation of 0.01 and groups of twenty-five individuals per cluster, the sample size was increased to 568 participants per group. The sample was further increased to 1,000 participants per group based on prior data, which indicated that approximately half of the study participants would be stationed in locations where it would be physically impossible to conduct STI and pregnancy screening at the second follow-up.

Statistical Analyses

Comparisons between experimental and control intervention participants were made using chi-square tests for differences in proportions using the SPSS CROSSTABS procedure. To assess whether the experimental intervention's effectiveness varied by the participants' sexual history, and to allow statistical adjustment for intervention group differences, a four-category measure (Sexual History) was constructed using the participants' self-reported sexual behavior in the three months prior to entering recruit training, their self-reported history of pregnancy and STIs, and the results of the baseline STI screening. The participants were categorized in one of four categories: (1) not sexually experienced; (2) sexually experienced with no history of pregnancy or STIs and not engaging in sexual intercourse in the prior three months or having one sexual partner and 100% condom use (No History-Safe); (3) sexually experienced with no history of pregnancy or STIs and engaging in sexual intercourse in the prior three months with two or more sexual partners and/or less than 100% condom use (No History-Unsafe); or (4) sexually experienced with history of pregnancy and/or STIs (History).

To evaluate the effectiveness of experimental intervention, separate multivariate logistic regression analyses were performed using the STATA LOGISTIC procedure for each outcome: (1) STIs (no vs. yes); (2) UPs (no vs. yes); (3) either STIs or UPs (no vs. yes); (4) Multiple Sexual Partners (zero or one partner vs. two or more partners); (5) Casual Sexual Partners (no vs. yes); and (6) Inconsistent Condom Use (100% vs. <100% condom use). The three independent variables in each regression model were: (1) Group, a dichotomy representing intervention group (experimental vs. control); (2) Sexual History, a four-level category of pre-intervention sexual history (Not Sexually Experienced, No History-Safe, No History-Unsafe, History); and (3) Latency, a continuous variable defined as the number of months between the baseline and second follow-up assessment. Latency was included because longer periods of time increased the

likelihood of an outcome occurring. In all the logistic regression analyses, standard errors were adjusted for clustering by platoon.

Since testing the effectiveness of the experimental intervention was operationalized as determining whether post-intervention prevalence of an outcome differed by intervention group, only results involving Group are presented below. For each outcome, the saturated model was evaluated first, but in all six cases the Group by History by Latency interaction was found to be non-significant ($p>.10$ for the Wald Statistic calculated by the STATA TEST procedure). The model containing the three two-way interactions (Group by History, Group by Latency, History by Latency) was then assessed. Only interactions that achieved statistical significance ($p<.10$) were retained in the models. For final models containing a statistically significant interaction involving Group, post-hoc analyses using a "simple effects" approach were performed using the STATA LINCOM procedure to calculate the odds ratio (OR) and corresponding 95% confidence intervals (CIs) for Group at varying levels of the other variable in the interaction. The minimum analytic model included the main effects of Group, Latency, and History. All models achieved adequate fit, defined as having a p-value greater than .20 on the Hosmer-Lemeshow goodness-of-fit chi-square test.

RESULTS

Study Participants

Between June 1999 and June 2000, all Marine Corps female recruits (N=2288) were approached for enrollment in the study. Of these individuals, 2157 (94.3%) voluntarily agreed to participate in the study; 1062 (49.2%) were assigned to the experimental intervention and 1095(50.8%) were assigned to the control intervention. Table 1 summarizes the baseline characteristics of the study participants, including sociodemographic risk markers and behavioral risk factors associated with STI acquisition and UPs, clinical factors, and STI screening results.

Four comparisons between experimental and control intervention participants on these variables were statistically significant at p<.10. Compared to the control intervention group, the experimental intervention group was slightly more likely to be married rather than single (p=.022), to have ever had a casual sexual partner (p=.043), to have used condoms less than 100% of the time (p=.068), and to have contracted *N. gonorrhoeae* (p=.035).

The total number of participants who completed the intervention and who graduated from recruit training is 1916 (88.8% of the baseline sample). Of these individuals, 939 (49.0%) and 977 (51.0%) were assigned to the experimental and control interventions, respectively.

Intervention Adherence

Adherence to both the experimental and control interventions was very high. Among participants assigned to the experimental intervention group, 900 (84.7%) attended all four sessions, 31 (2.9%) attended three sessions only, 120 (11.3%) attended one or two sessions only, and 11 (1.0%) were discharged from recruit training before attending any sessions. Among participants assigned to the control intervention group, 937 (85.6%) attended all four sessions, 33 (3.0%) attended three sessions only, 114 (10.4%) attended one or two sessions only, and 11 (1.0%) were discharged before attending any sessions.

Follow-up Assessments

At the first follow-up, 1743 participants (80.8% of the baseline sample, 91.0% of those completing the intervention) completed assessments. Of these individuals, 863 (49.5%) were in the experimental and 880 (50.5%) were in the control intervention. At the second follow-up, 1381 participants completed assessments (64.0% of the baseline sample, 72.1% of those completing the intervention). Of these individuals, 686 (49.7%) were experimental intervention participants and 695 (50.3%) were control intervention participants. Comparisons between experimental and control intervention participants on the same baseline characteristics displayed

in Table 1 again revealed four modest statistical differences. Relative to the control group, the experimental group was slightly less likely to be sexually experienced (83.6% vs. 87.1%, p=.070) and slightly more likely to have ever had a casual sexual partner (67.9% vs. 61.6%, p=.027), to have used condoms less than 100% of the time (79.6% vs. 75.4%, p=.084), and to have contracted *Neisseria gonorrhoeae* before entering the military (2.9% vs. 1.3%, p=.035). Among the participants in the second follow-up assessment, 856 (62.0%) completed both the self-report questionnaire and were screened for STIs and UPs, 486 (35.2%) completed questionnaires only, and 39 (2.8) were screened for STIs and UPs only.

Primary Outcomes

Post-intervention STIs were diagnosed in 120 (14.5%) of the 826 participants with data on this outcome, with 47 (5.7%) among experimental intervention participants and 73 (8.8%) among the control intervention participants. Post-intervention UPs were identified in 58 (7.0%) of 828 participants of which 27 (3.3%) were among experimental intervention participants and 31 (3.7%) were among control intervention participants. A post-intervention STI or UP (any primary outcome) was diagnosed in 171 (21.0%) of 814 participants including 70 (8.6%) among experimental group participants and 101 (12.4%) among control group participants.

Secondary Outcomes

At post-intervention, 738 (56.5%) of 1307 study participants reported engaging in sexual intercourse with multiple sexual partners, with 377 (28.8 %) among the experimental intervention group and 361 (27.6%) among the control intervention group. Similarly, 561 (42.9%) of 1307 study participants reported engaging in sexual intercourse with a casual sexual partner at post-intervention, with 285 (21.8 %) among the experimental intervention group and 276 (21.1%) among the control intervention group. Inconsistent use of condoms at post-intervention was reported by 969 (74.7%) of 1298 participants. Of these individuals, 474

(36.6%) were in the experimental intervention group and 495 (38.1%) were in the control intervention group.

Effectiveness of the Experimental Intervention

Post-intervention STIs or UPs

When post-intervention STIs and UPs was combined into a single outcome variable, a significant main effect for Group was observed (p=.043). A significantly higher proportion of the control intervention group (23.9%) than the experimental intervention group (17.9%) tested positive for a post-intervention STI or UP (OR=1.41, 95% CI=1.01-1.98).

Post-intervention STIs

For post-intervention STIs, a significant Group by Sexual History interaction (p=.023) was found. As shown in Table 2, among participants who had no pre-intervention history of STIs or pregnancy, but who engaged in risky sexual behaviors just prior to recruit training entry (No History-Unsafe), the control intervention group was significantly more likely than the experimental intervention group to acquire a post-intervention STI. There were no other significant Group differences in the likelihood of a post-intervention STI in the other three Sexual History categories.

Post-intervention UPs

No significant interactions involving Group were found for post-intervention UPs, nor was the main effect for Group significant (p=.815). Overall, 7.0% of the respondents had a UP, 6.7% of the experimental group and 7.3% of the control group, respectively. There was a significant History by Latency interaction (p<.001; data not shown).

Post-Intervention Multiple Sexual Partners

Both a Group by History interaction (p=.023) and a Group by Latency interaction (p=.042) were detected for post-intervention Multiple Sexual Partners. As shown in Table 3, among

participants who reported not being sexually experienced at baseline, control intervention participants were significantly more likely than experimental intervention participants to report having multiple sexual partners during the post-intervention period (OR=1.87, 95% CI=1.01-3.47). No Group differences were detected in the other three History categories. However, unexpectedly, participants in the control intervention were significantly less likely than participants in the experimental intervention to report having multiple sexual partners during the post-intervention period if the time between the baseline and second follow-up assessment was above the median at 16 months (OR=0.56, 95% CI=0.38-0.83). When the latency period is at or below the median, no significant Group differences were detected.

Post-Intervention Casual Sexual Partners

A significant Group by Sexual History interaction (p=.046) was detected for post-intervention Casual Sexual Partners. As shown in Table 4, among participants who reported not being sexually experienced at the baseline assessment, control intervention participants were significantly more likely to report having a casual sexual partner during the post-intervention period (OR=2.05, 95% CI=1.04-4.08). No other significant group differences were detected. The model also includes a significant History by Latency interaction (data not described).

Post-Intervention Inconsistent Condom Use

Although there is a significant main effect for History, there is no significant Group effect on post-intervention Inconsistent Condom Use (p=.318). Overall, 74.7% of respondents reported using condoms less that 100% of the time, 72.8% of the experimental intervention group and 76.5% of the control intervention group, respectively.

COMMENT

The primary goal of this research was to prevent *Chlamydia trachomatis, Neisseria gonorrhoeae*, *Trichomonas vaginalis*, and UPs in young women during their first year of military

service. Preventing these negative health outcomes may reduce women's risk of HIV transmission and PID and its sequelae of chronic pelvic pain, infertility, and potentially fatal ectopic pregnancy[1]. Unlike previous successful interventions that focused on preventing STIs in those seeking healthcare from STD clinics,[18, 19] our study is the first large-scale intervention trial to focus on preventing both STIs and UPs and is the first to target a large, non-clinic, and therefore, a non-health seeking sample of young women. Women, participating in our study self-selected to join the military, therefore our findings may not be generalizable to all women. However, this research provides some initial insights into STIs and their associated risk factors in young, non-college bound, sexually experienced women. Our participants were young (90% are between ages 17-21 years), healthy (88% did not have a history of STIs at baseline and 77% were asymptomatic for STIs), ethnically and racially diverse (44% are ethnic and racial minorities), and represented a vast geographic location of residence (every state and United States territory was represented).

Our findings indicate that women participating in the experimental intervention were less likely than the control intervention participants to have an UP or STI post-intervention (17.9% vs. 23.9%, respectively). No main effects were detected for STIs or UPs alone, or for self-reported sexual risk behavior. However, as expected, the intervention's effect differed by participants' pre-intervention level of sexual history. The experimental intervention had the most salient impact on reducing STIs in women who, prior to the intervention, had multiple sexual partners or used condoms inconsistently, (35% of the study participants). However, our intervention had no significant impact on women who were at no risk (not sexually experienced), at a relatively low level of risk (engaging in protective sexual behaviors) or were at increased risk (had experienced a pregnancy or STI) prior to entering recruit training. Similar to STIs, sub-group findings were detected for post-intervention self-reported sexual risk behaviors. That is,

women participating in the experimental intervention who were not sexually experienced, at baseline, were less likely to engage in sexual intercourse with multiple partners or with casual partners when they initiated sexual activity post-intervention. We found no significant group effect for post-intervention self-reported condom use. From our findings, we are unable determine why our intervention did not have a significant impact on women in the other risk categories. While it is beyond the goals of the current study, additional data analytic strategies that carefully examine other constructs identified in the IMB model may help to explain the variation in our research findings. For example, research by Shain and her colleagues[34] identified five factors (safer sex, mutual monogamy, low partner turnover, avoidance of unprotected sex with an untreated partner, and not douching) that explained the reduce risk status of women participating in their effective STI prevention intervention. Clearly, more thorough analyses of our findings will need to examine these, and perhaps, other military-specific factors to help explain our intervention findings. For example, it will be important for us to examine factors such as occupation specialty (whether it is primarily dominated my males), location of duty assignment (state-side or outside the continental United States), and the length of time of military service. These factors may provide further insight into the mechanisms by which our intervention had a significant effect on some women in our study and not others. Moreover, as suggested by the National Institutes of Mental Health Multisite HIV Prevention Trial (Project Light), beyond explaining cognitive-behavioral factors such as knowledge, skills, and self-efficacy, most of the effect of their successful intervention remained unexplained. Thus, it is possible that factors which contributed to lower rates of STIs and fewer risky sexual behaviors in sub-groups of the experimental intervention were not measured in this study.

Based on our findings, future interventions may do well to consider factors related to the design and content of the intervention in order to have a significant impact on women across all

risk categories. For example, future STI and UP intervention trials may have a more salient impact if they exceeded eight hours or if they more intensively emphasized components of the IMB model.

In addition to factors related to the intervention's content, the type of intervention can also be a factor. While it may be ideal to conduct individual-level, tailored interventions in clinic settings as it was the case for Project Respect[19] and Project SAFE,[18] it may not be feasible to conduct such interventions in large group settings such as schools, jails, youth detention facilities, or group homes. In these settings group-level interventions may be the only feasible approach for reaching a large number of individuals. Based on our findings, however, the variation in the participants' reproductive health history (both behaviors and health outcomes) must be taken into account when designing such group-level interventions. Additionally, group-level interventions should emphasize the continuum of sexual risk (no risk to increased risk) as part of the intervention's content.

Finally, the issue of assessment intervals may be a factor. Although we screened our participants at two points in time post-intervention, immediately after a leave (vacation), and again, on average, 14 months post-baseline, a potential limitation of our study design is that we did not screen the participants at more frequent intervals as indicated in earlier studies.[18, 19] To address this potential concern, we conducted additional data analyses that took into account interim STIs. The analyses reveal that our findings remain consistent even when self-report of STIs diagnosed during the interim period between the first and second follow-up assessments are included in the definition of a post-intervention STI. Once again, we found a significant Group by History interaction ($p=0.02$) for the post-intervention STI which covers the entire post-intervention period. Specifically, among participants who had no pre-intervention history of STIs or pregnancy but who engaged in risky sexual behaviors just prior to recruit training entry (No

History-Unsafe), the control intervention group was significantly more likely than the experimental intervention group to acquire a post-intervention STI (OR=2.30, CI=1.35-3.92). There were no other significant Group differences in the likelihood of a post-intervention STI in the other three Sexual History categories.

CONCLUSIONS

The high prevalence of sexual risk and STIs in this non-clinical sample of young women suggests the need for ongoing STI and UP interventions for young women who are not seeking reproductive health care. The findings of this randomized controlled trial indicate that cognitive-behavioral, group-level interventions are effective strategies to prevent STIs and UPs and reduce sexual risk behaviors in large numbers of young women who are risk but may not access the health care system. Such settings may include college dormitories, job training programs such as Job Corps, youth detention facilities, and group homes.

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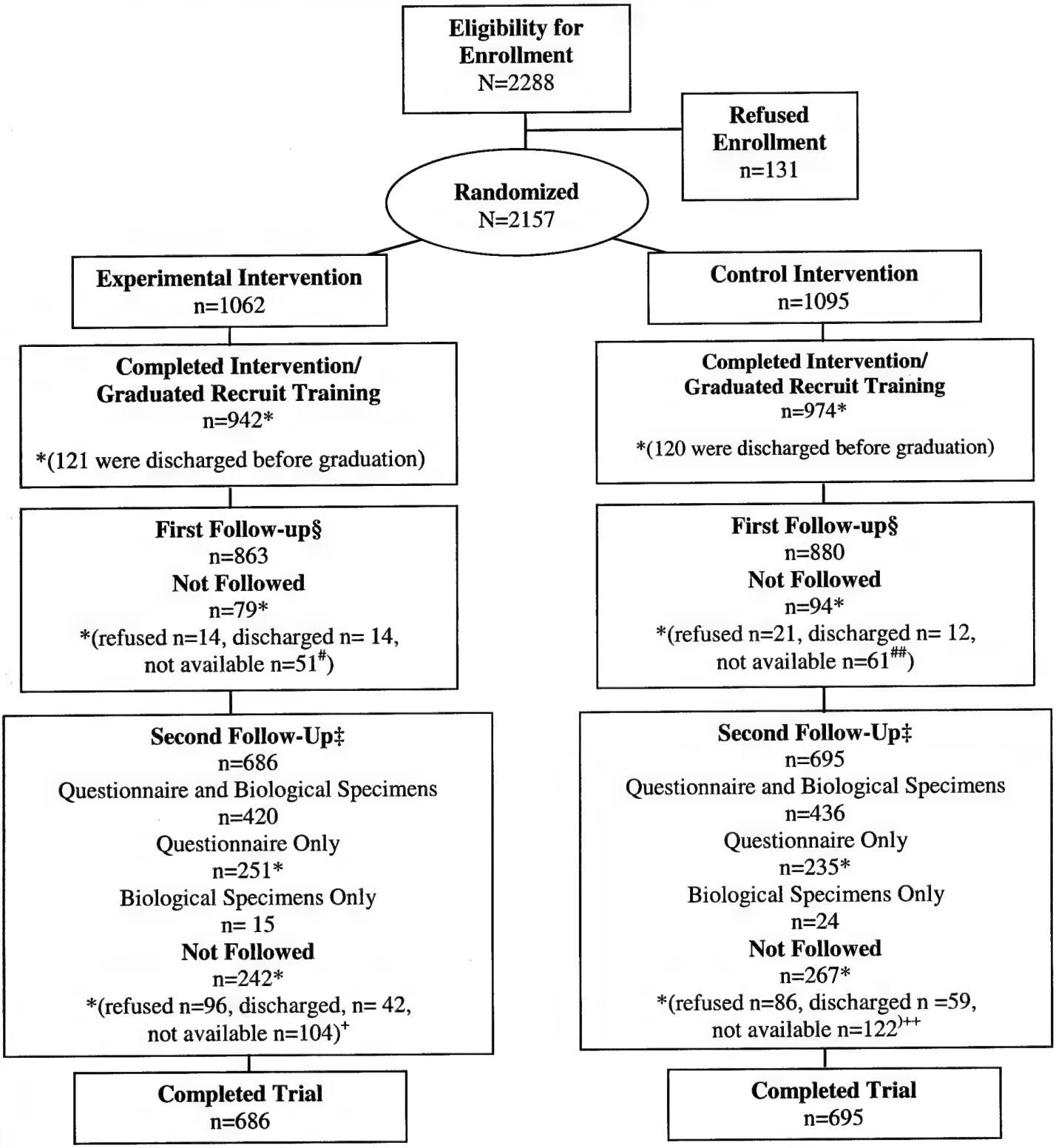
Figure 1. Progress of participants through the intervention trial



#23 were reservist and not on active duty; ##25 were reservist and not on active duty

§This assessment occurred, on average, one month after graduation from recruit training (median =34.5 days, range=11-146 days) due to varying days of leave

‡This assessment occurred, on average, 14 months (median =12.8 months, range=6.2-31.7 months) after the baseline assessment.

+30 were reservists and were not on active duty; ++34 were reservist and were not on active duty

Figure 2. Overview of the Experimental Intervention

	Session 1	Session 2	Session 3	Session 4
Overall Goals	Increase knowledge about UPs, STIs, including HIV/AIDS. Modify values, beliefs, and attitudes that impact sexual behavior.	Increase knowledge about hormonal and barrier contraceptives. Build communication skills to prevent risky sexual behaviors and increase contraceptive use.	Increase knowledge about the signs, symptoms, and consequences of STIs/HIV/AIDS. Increase knowledge about the transmission and prevention of STIs/HIV. Build communication skills to prevent STI/HIV.	Modify attitudes about the effects of alcohol and its relationship to sexual risk behaviors. Build refusal communication skills. Build condom use skills. Increase awareness about how military life can impact sexual decision-making and health.
Educational Objectives	Increase awareness on how participants' values and attitudes shape their views of themselves as sexual beings. Evaluate how participants' values impact their decisions about UP/STI prevention. Educate participants about risks associated with UPs, STIs. Provide basic facts on male and female reproductive anatomy and physiology. Familiarize participants with the basic gynecological examination. Assist participants to develop and articulate their military career goals. Examine how reproductive health behaviors may impact participants' career goals.	Provide historical overview of contraceptive methods. Discuss factors that influence women's decision about contraceptive use/nonuse. Discuss pros and cons of various contraceptive methods. Increase awareness about the impact that UPs may have on participants' personal lives and career. Examine the range of options available for UPs and sources of social support. Build communication skills on sexual behavior and contraceptive use with a sexual partner. Discuss participants' feelings, attitudes about contraceptive use and sexual partner communication	Describe the risks and transmission of STIs/HIV. Discuss risky sexual practices Have participants self-assess their STI/HIV acquisition risk. Increase participants' awareness of how assumptions about a potential sexual partner can influence their risk perceptions. Describe the signs, symptoms, and consequences of STIs/HIV/AIDS. Build skills to communicate with potential sexual partners. Discuss how HIV infection is a reality among military personnel. Examine the impact of HIV on families and lives of those infected.	Describe alcohol use effects. Simulate social and emotional challenges women face early in their military career (e.g., during Service School, deployment). Describe the steps required for proper use of condoms. Examine barriers to consistent condom use. Provide an opportunity for participants to practice proper condom use skills. Build communication skills to exit risky sexual situations. Discuss the appropriate time to seek reproductive health care. Discuss barriers and benefits to seeking reproductive health care.

Table 1. Baseline Characteristics of the Study Participants by Intervention Group

Variable	Experimental Intervention Group	Control Intervention Group	Total[§]
	n (%)	n (%)	N (%)
	1062 (49.2)	1095 (50.8)	2157 (100)
Age			
17-18	561 (52.8)	603 (55.1)	1164 (54.0)
19-21	389 (36.6)	391 (35.7)	780 (36.2)
≥ 22	112 (10.5)	101 (9.2)	213 (9.9)
Race			
Caucasian	593 (55.8)	613 (56.0)	1206 (55.9)
Latina	211 (19.9)	215 (19.6)	426 (19.7)
African American	165 (15.5)	183 (16.7)	348 (16.1)
Asian/Pacific Islander	29 (2.7)	38 (3.5)	67 (3.1)
Native American	29 (2.7)	24 (2.2)	53 (2.5)
Other/Mixed	35 (3.3)	22 (2.0)	57 (2.6)
Marital Status[@]			
Single (Never Married)	957(90.3)	1017 (93.1)	1974 (91.7)
Married	88 (8.3)	58 (5.3)	146 (6.8)
Separated/Divorced	15 (1.4)	17 (1.6)	32 (1.5)

Table 1. Baseline Characteristics of the Study Participants by Intervention Group (cont.)

Geographic Location of Residence			
Urban	839 (79.1)	860 (78.8)	1699 (78.9)
Rural	222 (20.9)	231 (21.2)	453 (21.1)
Sexually Experienced*			
Yes	892(84.7)	949 (86.8)	1841 (85.8)
No	161 (15.3)	144 (13.2)	305 (14.2)
Number of Sexual Partners (Lifetime)#			
1	149 (17.1)	174 (18.9)	323 (18.0)
≥ 2	722 (82.9)	745 (81.1)	1467 (82.0)
Number of Casual Partners (Lifetime)#,@			
0	281 (32.6)	338 (37.1)	619 (34.9)
≥ 1	582 (67.4)	572 (62.9)	1154 (65.1)
Number of Sexual Partners (3 months)#			
0	142 (16.1)	132 (14.2)	274 (15.2)
1	513 (58.3)	576 (62.1)	1089 (60.2)
≥ 2	225 (25.6)	220 (23.7)	445 (24.6)
Frequency of Contraception Use (Lifetime)#			
Never/Sometimes	299 (34.1)	298 (32.0)	597 (33.0)
Usually/Always	577 (65.9)	634 (68.0)	1211 (67.0)
Frequency of Condom Use (Lifetime)#,$			
< 100%	703 (80.3)	708 (76.7)	1411 (78.4)
100%	173 (19.7)	215 (23.3)	388 (21.6)

Table 1. Baseline Characteristics of the Study Participants by Intervention Group (cont.)

History of Pregnancy (Self-report)[#]			
Yes	152 (17.1)	146 (15.5)	298 (16.3)
No	739 (82.9)	793 (84.5)	1532 (83.7)
History of STIs (self-report)[#]			
Yes	104 (11.6)	105 (11.2)	209 (11.4)
No	789 (88.4)	835 (88.8)	1624 (88.6)
STIs (screening)[+]			
Any STI	118 (11.7)	131(12.4)	249 (12.0)
C. trachomatis	99 (9.5)	110 (10.2)	209 (9.8)
N. gonorrhoeae[@]	28 (2.7)	15 (1.4)	43 (2.0)
T. vaginalis	16 (1.6)	14 (1.3)	30 (1.5)
Pre-Intervention Sexual History			
Not Sexually Experienced	161 (15.8)	144 (13.6)	305 (14.7)
No History-Safe	193 (19.0)	221 (20.8)	414 (19.9)
No History-Unsafe	352 (34.6)	375 (35.3)	727 (35.0)
History of Pregnancy and/or STIs	311 (30.6)	322 (30.3)	633 (30.4)

[*] Reported engaging in vaginal sexual intercourse at least once in the past.

[#] Include only the sexually experienced participants.

[+] All participants were screened for STIs.

[@] $p<.05$

[$] $p<.10$

Table 2. Post-Intervention STIs: Intervention Group by Sexual History Interaction

Sexual History	Percent Positive		Odds Ratio[#] (95% CI)
	Experimental Intervention Group	Control Intervention Group	
Not Sexually Experienced	10.0%	15.8%	1.68 (0.53-5.31)
No History-Safe	10.8%	10.0%	0.89 (0.34-2.31)
No History-Unsafe	8.0%	21.8%	3.24 (1.74-6.03)[*]
History of STIs/Pregnancy	18.6%	18.2%	0.96 (0.45-2.06)

[#]The odds ratio is statistically adjusted for the time between the pre-intervention and post-intervention assessments; the standard error is adjusted for clustering by platoon.

[*] $p<.001$

Table 3. Multiple Sexual Partnerships Post-Intervention: Intervention Group by Sexual History and Intervention Group by Latency Interactions

Sexual History	Percent Positive		Odds Ratio[#] (95% CI)
	Experimental Intervention Group	Control Intervention Group	
Not Sexually Experienced	25.7%	35.4%	1.87 (1.01-3.47)*
No History-Safe	54.5%	60.3%	1.45 (0.88-2.37)
No History-Unsafe	70.5%	59.6%	0.70 (0.45-1.09)
History of STIs/Pregnancy	59.6%	55.6%	0.93 (0.59-1.47)
Latency[+]			
10 months	52.1%	44.0%	0.87 (0.49-1.53)
13 months	53.5%	58.4%	0.70 (0.45-1.09)
16 months	63.6%	53.3%	0.56 (0.38-0.83)**

[#]The odds ratio is calculated with Latency held constant at 13 months; the standard error is adjusted for clustering by platoon.

[§]The odds ratio is calculated with Sexual History held constant at No History-Unsafe; the standard error is adjusted for clustering by platoon.

[+]Proportions are calculated for the 3-month interval with the row header as midpoint.

* $p<.05$

** $p<.005$

Table 4. Casual Sexual Partnerships Post-Intervention: Intervention Group by Sexual History Interaction

Sexual History	Percent Positive		Odds Ratio[#] (95% CI)
	Experimental Intervention Group	Control Intervention Group	
Not Sexually Experienced	18.1%	30.5%	2.05 (1.04-4.08)*
No History-Safe	40.2%	42.6%	1.11 (0.71-1.75)
No History-Unsafe	54.9%	46.0%	0.69 (0.47-1.23)
History of STIs/Pregnancy	44.1%	42.8%	0.93 (0.58-1.48)

[#]The odds ratio is statistically adjusted for the time between the pre-intervention and post-intervention assessments; the standard error is adjusted for clustering by platoon.

*$p<.05$

Appendix 1.b.

Shafer MA, Moncada J, Boyer CB, Betsinger K, Flinn SD, Schachter J. Comparing the FVU, Self-collected Vaginal Swabs and Endocervical Specimens to Detect *C. trachomatis* and *N. gonorrhoeae* using Nucleic Acid Amplification Tests. *Journal of Clinical Microbiology*, 41(9):4395-99, 2003.

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Comparing First-Void Urine Specimens, Self-Collected Vaginal Swabs, and Endocervical Specimens To Detect *Chlamydia trachomatis* and *Neisseria gonorrhoeae* by a Nucleic Acid Amplification Test

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We set out to determine the prevalences of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* by ligase chain reaction as well as to determine the prevalence of *Trichomonas vaginalis* by culture in a large and diverse national sample of non-health-care-seeking young women entering the military; we also sought to compare the abilities of three different techniques of collecting specimens (first-void urine, self-collected vaginal swab, and clinician-collected endocervical swab) to identify a positive specimen. A cross-sectional sample of young women was voluntarily recruited; as a part of their routine entry pelvic examination visit, they completed a self-administered reproductive health questionnaire and provided first-void urine (used to detect *C. trachomatis* and *N. gonorrhoeae*) and self-collected vaginal swabs (used to detect *C. trachomatis*, *N. gonorrhoeae*, and *T. vaginalis*). The number of positive tests divided by the number of sexually active women screened by each sampling method determined the rates of prevalence. The rate of infection with any of the three sexually transmitted diseases (STDs) tested was 14.1%. The total positive rates for each STD (identified by ≥1 specimen) were the following: for *C. trachomatis*, 11.6%; *N. gonorrhoeae*, 2.4%; and *T. vaginalis*, 1.7%. The proportions of positives identified by specimen type were, for *C. trachomatis* and *N. gonorrhoeae*, respectively, endocervix, 65 and 40%; urine, 72 and 24%; and vagina, 81 and 72%. The proportions of positives when specimen results were combined were, for *C. trachomatis* and *N. gonorrhoeae*, respectively, cervix plus urine, 86 and 49%; cervix plus vagina, 91 and 93%; and vagina plus urine, 94 and 79%. We concluded that STDs were epidemic in this population. Self-collected vaginal swabs identified the highest number of positive test results among single specimens, with the combined cervix-vagina results identifying the highest number of positive results. Self-collected vaginal swab collections are a feasible alternative to cervical specimen collections in this population, and the use of multiple types of specimens increases the positive yield markedly.

Chlamydia trachomatis remains epidemic among sexually active young women (5). Health policy organization guidelines recommend annual chlamydial screening of sexually active adolescent and young adult females (1, 2, 29). Nucleic acid amplification technique (NAAT) applied to endocervical samples has proven to be a sensitive nonculture method to screen young women for *C. trachomatis*, with sensitivities ranging from 75 to 100% and with many reporting sensitivities greater than 90% (6, 7, 21, 22, 27, 30, 31). A further advance has been the application of the NAAT to first-void urine (FVU) samples to detect *C. trachomatis* with reported sensitivities of 50 to 95% (6, 7, 15, 22, 25, 27, 30, 31). This noninvasive form of specimen collection has been shown to be a cost-effective tool for chlamydial screening when compared to endocervical swabs because such collections do not require invasive pelvic examinations (24). Finally, the self-collected vaginal sample (e.g., swabs, tampons, and wash) has been a recent additional source for sexually transmitted disease (STD) specimens from young adult women with reported sensitivities by NAATs ranging from 75 to 100% for the detection of *C. trachomatis* (6–8, 12, 18, 19, 26, 28, 33), although this technique has not been approved by the U.S. Food and Drug Administration to date. Performances of the NAATs applied to *Neisseria gonorrhoeae* have been reported to be similar to those with *C. trachomatis*, with endocervical sample sensitivities of 89 to 97%, vaginal sample sensitivities of greater than 90%, and FVU sample sensitivities between 65 and 93% (4, 7, 8, 16, 30, 31).

It is difficult to compare the performance profiles of NAATs across studies, as they differ widely by the choice of STD test, specimen type, and the population studied. Comparative evaluations of different test systems and specimen sources, especially of self-collected specimens, are essential to the development of more consumer-friendly STD screening tests. However, there are few data published in which NAATs were used to compare three different anatomic specimens collected in parallel from the same female subject. In one such study, PCR was applied to identify *C. trachomatis* and *N. gonorrhoeae* from multiple specimen types (FVU, vaginal, and endocervical) during screening of 349 women from remote towns in Western Australia having gynecologic assessments (7) and found that the self-collected vaginal swab method identified

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more positive tests for both organisms than did samples from the other two anatomic sites. With this in mind, the present study reports the results of a ligase chain reaction assay for *C. trachomatis* and *N. gonorrhoeae* applied to FVU, self-collected vaginal, and clinician-collected endocervical specimens in a large cohort of young women in the United States upon their entry into the military.

MATERIALS AND METHODS

Subjects and recruitment. Young women entering 13 weeks of recruit training at the U.S. Marine Corps Recruiting Depot in Parris Island, S.C., were recruited to participate in "Focus—Fitness For Life," a cognitive behavioral intervention designed to decrease STD acquisition and unintended pregnancy during their first year of enlistment. Participation was voluntary and required informed written consent in accordance with the requirements set by the military and university institutional review boards for human research. This study represents the baseline sociodemographic and biologic data. Between June 1999 and June 2000, 2,288 women voluntarily consented to participate in the study, and 2,157 (94%) women provided written consent.

Procedures. Participants underwent a routine pelvic examination with STD and Papanicolaou smear screening within 2 weeks of arrival. A self-report questionnaire and specimen collection (cervical, FVU, and two self-administered vaginal swab specimens) were carried out during this examination period.

Questionnaire. A self-report questionnaire about demographic characteristics, health and risk behaviors, and a reproductive clinical history (e.g., contraception, STD history, and pregnancy history, among other risk factors) was administered just prior to the routine pelvic examination.

Specimen collection and processing. Participants were instructed on the proper self-collection of the FVU (i.e., filling the first 20 ml in a marked cup) and vaginal specimens used to screen for *C. trachomatis*, *N. gonorrhoeae* (insert Dacron swab 2 in. [LCx STD kit], rotate around vagina three times), and *Trichomonas vaginalis* (repeat vaginal collection procedure with second swab [cotton]). Both swabs were immediately placed into a sterile screw-cap plastic specimen collection tube and immediately transported with the urine specimens to the clinic laboratory by a clinic assistant. The specimens were inoculated into their respective media within 5 min after the participant completed the self-administered vaginal specimen collection. After the urine and vaginal specimens were completed, the participants proceeded to their scheduled pelvic examination, during which the clinician first obtained the endocervical specimen according to the LCx protocol (for detection of *C. trachomatis* and *N. gonorrhoeae*) and then used a cytobrush to collect the Papanicolaou smear specimen.

Vaginal and urine specimens targeted for identification of *C. trachomatis* and *N. gonorrhoeae* were kept at 4°C immediately after collection and frozen at −70°C in the hospital freezer within 24 h of collection. They were shipped by overnight airfreight to the author's laboratory (J. Schachter) in batches, with the cold chain maintained by using specialized shipping containers containing dry ice. Endocervical specimens for *C. trachomatis* and *N. gonorrhoeae* were transported routinely, with the cold chain maintained, to the Naval Hospital laboratory for processing within 6 h of collection. Endocervical, vaginal, and FVU samples for *C. trachomatis* and *N. gonorrhoeae* were processed using LCx (4). In order to decrease costs and avoid unnecessary duplication, the endocervical swabs for *C. trachomatis* and *N. gonorrhoeae* were processed routinely by the Naval laboratory using the same LCx methodology as was used in the author's laboratory (J. Schachter).

The second self-collected vaginal swab was tested for *T. vaginalis* using the Trichomonas In-Pouch TV (Biomed Diagnostics, San Jose, Calif.) according to the manufacturer's instructions. These swabs were incubated in pouches at collection at 37°C and read for the presence of *T. vaginalis* at 2 and 5 days of inoculation by trained research assistants. Papanicolaou smears were prepared by the collecting clinician and sent to a local Navy-approved hospital-based cytology laboratory.

Regarding the problem of specificity encountered with the LCx system in 2001, most of the LCx assays were completed before 1 February 2001 prior to problems encountered with the manufacturer's specificity due to changes in components of the assay system. After that date, all positives (our final batch of specimens) were retested again before a positive result was reported, as required. If the repeat specimen-to-cutoff ratio was ≥1.0, it was read as a true positive; if the ratio was read as <1.0, it was considered a false positive and thus reported as a negative result. (Eleven positives out of 178 specimens in the final batch of specimens were found and confirmed positive on retesting during the last month of specimen processing, March 2001.)

Data analysis. This study compares the abilities of three different specimen sites (endocervical, self-collected vaginal, and FVU) to identify a positive *C. trachomatis* and *N. gonorrhoeae* test. That is, any positive test by any collection method was considered the standard by which any single or combination of collection technique performances was measured.

RESULTS

Participants included 2,157 women (94% of those eligible), of which 1,841 (85%) reported ever having been sexually active. Only data from sexually active women were included in the present study.

Sociodemographic and reproductive health history. This largely young (median age of 18 years, with 74% of women ranging from 17 to 19 years old), unmarried (92%), and ethnically diverse (43% racial or ethnic minority) cohort represents a "national" sample of young women (i.e., from all 50 states, Guam, Puerto Rico, and the U.S. Virgin Islands) who were not seeking health care services but who received a screening reproductive health assessment as part of their entry into the military. Most women did not report a history of a pregnancy (84% never pregnant), did report a history of sexual intercourse within the previous 3 months (85%), and reported having more than one lifetime partner (82%). Forty-four percent reported having ≥5 lifetime partners. At the last instance of intercourse, almost one-third used either no method or withdrawal only as a contraceptive technique, 20% used oral contraceptive pills, 7% used insertable (diaphragms or contraceptive jelly or foam) or injectable contraceptives, and 41% used condoms only as their contraceptives of choice (Table 1).

Prevalences of *C. trachomatis*, *N. gonorrhoeae*, and *T. vaginalis*. The rate of infection with any of the three STDs tested was 14.1%. The total positive rate for each STD (identified by ≥1 specimen) follows: for *C. trachomatis*, 11.6%; *N. gonorrhoeae*, 2.4%; and *T. vaginalis*, 1.7% (Table 2).

Adequacy of the Papanicolaou smear. As a measure of endocervical specimen adequacy for Papanicolaou specimen collection (presence of endocervical cells), we found that adequate cytology was achieved for >93% of cases.

Performances of *C. trachomatis and N. gonorrhoeae* by specimen type. All performance data are relative since the "gold standard" used here is based on the sum of "any positive" test from any specimen. (Specificities and predictive positive values based on our gold standard were 100%, and predictive negative values were 95 to 100% for both *C. trachomatis* and *N. gonorrhoeae* by any specimen type.) Positive results by specimen type are found in Table 2. The self-collected vaginal swab ranked highest in ability to detect a positive result among any of the three types of specimen collection for both *C. trachomatis* (81%) and *N. gonorrhoeae* (72%). For *C. trachomatis*, the urine specimen (72%) was the next-best single-specimen performer, followed by the endocervical specimen (64%). Combining the FVU specimen with the vaginal specimen boosted the detection rate of *C. trachomatis* to 94%, the highest detection rate of any single specimen or combination thereof. As expected, any combination of tests outperformed any single test.

The ability of the LCx to detect *N. gonorrhoeae* by specimen

TABLE 1. Sociodemographic characteristics of sexually active female military recruits (n = 1,841)

Variable	Value
Mean age (range)	19.1 years (17–33)[a]
Ethnicity	
White	57%
Hispanic	19%
African-American	16%
Other	8%
Marital status	
Never married	90%
Married	8%
Separated or divorced	2%
Age of sexual debut median (range)	16 years (6–27)
Years sex active median (range)	3 years (1–16)
Pregnancy ever	16%
STD ever ("Told by MD")	11%
Partners in last 3 months	
Did not have sex	15%
1 partner	60%
>1 partner	25%
≥1 Casual partner	25%
Contraception method for last sexual intercourse	
No method or withdrawal only	32%
Oral contraceptive pills only	13%
Oral contraceptive pills and condoms	7%
Medroxyprogesterone acetate or levonorgestrel only	5%
Medroxyprogesterone acetate or levonorgestrel and condoms	2%
Condoms only	41%

[a] Ninety percent of women were less than 21 years old.

type was poorer in all single-specimen categories than the results for *C. trachomatis*. As stated earlier for *C. trachomatis*, the vaginal specimen had the highest detection rate of positives among the single-specimen evaluations (72%) and, if combined with the endocervical specimen, the positive detection rate was boosted to 93%. However, compared to vaginal samples, the endocervical and urine specimens performed particularly poorly for the detection of *N. gonorrhoeae*.

DISCUSSION

Overview. This study represents a large cross-sectional sample of young women (n = 1,841) from every U.S. state and territory who were not seeking health care but who were screened for multiple STDs from multiple genitourinary specimens. The resultant study population was largely unmarried and young, as three-quarters of the participants were 17 to 19 years old. They were also at high risk for STD acquisition, as 50% reported no use of barrier contraceptives at the time of last intercourse, almost half stated that they had already had five or more lifetime partners, and a quarter of participants had had a "casual" partner in the past 3 months alone.

Prevalence of *C. trachomatis*, *N. gonorrhoeae*, and *T. vaginalis*. The overall total STD prevalence rate for any of the tested organisms was very high (14.1%), with a detection rate of 11.6% for *C. trachomatis*, 2.4% for *N. gonorrhoeae*, and 1.7% for *T. vaginalis*. Our *N. gonorrhoeae* rate is similar to rates described for other young populations who are not seeking health care when screened (2%) (17) but was lower than the 5% found for *N. gonorrhoeae* among enlisted women seeking care at a military clinic for STD treatment (20).

Our prevalence rate for *T. vaginalis* is lower than many reports of testing in high-risk populations (7, 11). It is more similar to the 5% prevalence determined for enlisted Army women attending a military epidemiology clinic (STD clinic) using the same trichomonal culture technique as that used in the present study (20). Lower trichomonal rates may be explained in part by the fact that our population is the only study among those cited that represents a group of healthy young women who were not seeking health care at the time of the screening, as they were recruits at the time of entry into the military. It may also be that we had some false-negative results, as our self-administered swabs were transported dry to the laboratory before immediately being inoculated into the growth media, even though transport was done within 5 min of collection. Increasing loss of positivity for *T. vaginalis* over time as determined by repeated wet-mount examinations has been documented previously (14).

Finally, our overall rate for chlamydial infection, based on the sum of any positive result for any specimen, was 11.6%. Detection rates for chlamydia by specimen type follow: endocervix (7.5%), FVU (8.4%), and self-administered vaginal swab (9.6%). Our prevalence for chlamydia by FVU is similar to that reported for a young Army recruit population, the results for which were achieved by the use of ligase chain reaction applied to the FVU (9.2%) (9).

Determining the best specimen type to detect positives during screening efforts. Given the STD risk for these young women and the need to screen large numbers of young women in a short period of time (upon entry into the military), it is important to maximize the identification of these undetected STD infections while minimizing collection invasiveness, clinician and client time, and cost of collection and processing. In evaluating the individual specimen collection methods, the

TABLE 2. STD prevalences and ability to detect a positive result by specimen type

Specimen type(s)	% Prevalence of STDs caused by[a]:		% of specimens positive for[b]:	
	C. trachomatis	*N. gonorrhoeae*	*C. trachomatis*	*N. gonorrhoeae*
Any positive specimen	11.6 (207/1,786)	2.4 (43/1,785)		
Endocervix	7.5 (134/1,786)	1.0 (17/1,785)	65 (134/207)	40 (17/43)
Urine	8.4 (145/1,728)	0.6 (10/1,727)	72 (145/201)	24 (10/41)
Vagina[c]	9.6 (167/1,746)	1.8 (31/1,744)	81 (167/206)	72 (31/43)
Endocervix and urine			86 (176/205)	49 (21/43)
Endocervix and vagina[c]			91 (188/207)	93 (40/43)
Vagina[c] and urine			94 (194/206)	79 (33/42)

[a] Values in parentheses are numbers of women positive for an STD(s)/total number of women. Denominators may differ due to missing specimens.

[b] Referent is positive result with any specimen, so values in parentheses are numbers of positive specimens of given type/total number of positive specimens. Denominators may differ due to missing specimens.

[c] Self-collected vaginal swab.

self-collected vaginal swab was found to have the highest rate of detecting positive tests for both *C. trachomatis* and *N. gonorrhoeae* infection. These findings are similar to the few works available that compare the performances of all three collection specimens processed by NAATs, which showed that the vaginal specimen had the greatest ability to detect *C. trachomatis* and *N. gonorrhoeae* by LCx (4, 10) and by PCR (3, 7), with mixed results for the next-higher performer using LCx or PCR applied to urine and endocervical specimens.

Our endocervical specimens performed the most poorly of our three specimens for the positive detection of chlamydia. Such findings differ from several previously published studies (4, 10). It may be that we had a number of false-negative endocervical tests due to differences in specimen collection (13, 32), transport, and processing, as the endocervical samples were processed in a different laboratory from that used for our vaginal and urine specimens. For example, it has been clearly shown that the cellular quality of the specimen collected has a direct impact on the ability to detect a true positive, whereby specimens deemed to have adequate cellularity were more likely to have a positive *C. trachomatis* result than those that had inadequate cells on smear (13, 32). Furthermore, the ability of the LCx to detect *N. gonorrhoeae* was unacceptably poor, especially with respect to the urine and endocervical specimens. It may be that our low prevalence for *N. gonorrhoeae* among this population of non-health-care-seeking asymptomatic young women had a negative impact on the ability of the LCx to yield an accurate result.

We also found an improvement in the identification of positive results when more than one method was used to screen. This finding was also shown using PCR on the same three specimen collection combinations in a population of women (7). The combination of the vaginal and urine specimens is of interest since those two methods represent self-collected specimens that require no additional clinician time to collect to enhance detection of positives. The combination of endocervical and vaginal sampling yielded a significant boost in detection for both *C. trachomatis* and *N. gonorrhoeae* (*T. vaginalis* was collected only by using the self-collected swab). Such findings may be translated into recommending that the clinician obtain a combined endocervical and vaginal sample on the same swab during a pelvic examination. This interpretation of the findings needs to be further evaluated.

Seeking the ideal STD screening specimen. Vaginal swabs proved to be the best single method at identifying positive results. They were also very readily accepted as a specimen source among these young women. STD screening by urine samples and vaginal swabs is much preferred by young women when compared to the traditional collections performed during routine pelvic examinations. In a study from our group of adolescent young women attending a teen clinic for a routine pelvic exam, a nonmedical research assistant instructed the young women regarding how to collect the FVU and self-administered vaginal swabs prior to their scheduled routine pelvic exam. After the visit, the young women were asked to rank their preference for specimen type should they need screening for STDs in the future. Not surprisingly, they ranked the urine first and the pelvic examination last, with the vaginal swab collection ranked intermediately between the two (23). Vaginal specimens are an attractive alternative to FVU because vaginal swab specimens remain stable (i.e., they do not require immediate cold storage) enough to be shipped over a few days' time to a remote laboratory. Vaginal specimens also require fewer steps to process than do urine samples in the laboratory. With both patient acceptance and ease of transport and processing, vaginal specimens might become the specimen of choice as work progresses toward the development of future home testing kits, for example. The vaginal specimen approaches the ideal screening specimen. It is noninvasive, it is not linked to a pelvic exam or to the requirement of a health professional or clinic for adequate collection, it is an easy and stable format for transport, including mail transport, and it offers ease of laboratory processing—among other attributes. Clearly, more attention is needed to evaluate specimen collection types, especially vaginal swabs, as we continue to develop and evaluate new STD test systems. In this same study of screening preferences of young sexually active women, 25% refused to participate in the collection of vaginal specimens giving such reasons as "lack of time," not wanting to "touch myself," and lack of trust in the new technique compared to a clinician's collection performed at the routine pelvic examination (23). It must be noted that these young women were already sexually active at the time of the scheduled routine pelvic examination.

Summary. Young ethnically diverse young women entering the military from across the United States have very high rates of *C. trachomatis* infection. To ameliorate this continued epidemic of infection among our young women nationwide, it is necessary to increase screening for asymptomatic infection. Evaluating the performance of noninvasive collection of specimens such as urine and self-collected vaginal swabs furthers our knowledge of the ideal acceptable and sensitive screening specimen for the target population. This research emphasizes the importance of beginning to evaluate the efficacy of specific screening specimens and clinical algorithms for young women who are not symptomatic and are not seeking health care, especially within the STD-public health clinic setting, as performance profiles may differ. The final goal is to develop cost-effective screening tools that are acceptable, stable and accurate, and widely available to young women who are at risk for STD acquisition.

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Appendix 1.c.

Yen S, Shafer MA, Moncada J, Campbell CJ, Flinn SD, Boyer CB. Prevalence and Clinical Correlates of Bacterial Vaginosis among Sexually Experienced and Non-Sexually Experienced Young Women Entering The Military. Obstetrics and Gynecology. In Press, 2003.

Prevalence and Clinical Correlates of Bacterial Vaginosis Among Sexually Experienced and Non-sexually Experienced Young Women Entering the Military

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Running Head:
BV: PREVALENCE, CORRELATES

Précis

Bacterial vaginosis (BV) occurs commonly in the sexually experienced and inexperienced, is related to current *C. trachomatis*, and is inversely related to hormonal contraceptive use.

ABSTRACT

OBJECTIVE: To determine the prevalence of bacterial vaginosis (BV) by Nugent Gram stain criteria in a non-clinic national sample of young women entering recruit training; to determine clinical associations with BV; and to evaluate the performance of a pH test card and Papanicolaou smear against Gram stain as screening tools for BV.

METHODS: A cross-sectional study of 1938 women was conducted. Self-collected vaginal swabs were applied to a colorimetric pH test card (FemExam® pH and Amine TestCard™, Litmus Concepts, Inc, Santa Clara, CA, USA) and a glass slide for Gram stain evaluation using the Nugent criteria. Papanicolaou smears and samples for sexually transmitted diseases screening were collected during routine entry pelvic examinations.

RESULTS: BV prevalence was 27%, with 28% in sexually experienced and 18% in non-sexually experienced women (p=.001). BV prevalence was 11% in Asian/Pacific-Islanders which was significantly different from all other ethnic groups (p=.017). Clinically, BV was directly related to self-report of vaginal discharge (p=.001), self-report of vaginal odor (p<.001), current *Chlamydia trachomatis* infection (p=.002), and inversely related to hormonal contraceptive use (p=.013). Compared to Gram stain, the sensitivities/specificities for BV diagnosis were: colorimetric pH test 72%/67% and Papanicolaou smear 72%/79%.

CONCLUSION: Among this diverse sample of young women, BV occurs commonly in both sexually experienced and inexperienced young women and differs by race/ethnicity. The pH colorimetric test and Papanicolaou smear performed moderately well as screening tools for BV. The inverse relationship of BV with hormonal contraceptive use and its direct relationship with *C. trachomatis* need further study.

INTRODUCTION

Bacterial vaginosis (BV) is the most common cause of vaginal discharge in the United States.[1] It is a clinical syndrome associated with the presence of a group of microorganisms rather than a single etiologic agent. BV is characterized by a shift in the vaginal flora from the normal *Lactobacillus*-dominant species to a mixed flora, including *Gardnerella vaginalis*, *Bacteroides* species, *Mobiluncus* species, and *Mycoplasma hominis*. BV is associated with reproductive health morbidity, including pelvic inflammatory disease,[2-4] preterm birth, premature rupture of membranes,[5] chorioamnionitis,[6] spontaneous abortion,[7] and post-gynecologic surgery infection.[8] From the available studies that focus largely on sexually transmitted disease (STD) clinic patients and pregnant women, BV prevalence is estimated to range from 7% among asymptomatic women attending general practice clinics[9] to 46% among women attending STD clinics.[10]

Traditionally, BV diagnosis is defined clinically by the presence of three of the four Amsel's criteria: (1) vaginal pH >4.5; (2) presence of adherent white discharge; (3) detection of "clue cells" by wet mount; and (4) presence of an amine odor after the addition of potassium hydroxide also known as the "Whiff" test.[11] Additional laboratory-based methods of BV diagnosis have included: culture for *G. vaginalis*, biochemical tests for metabolic by-products of vaginal bacteria (gas chromatography)[11], and colorimetric tests for enzymes produced by BV organisms (sialidase)[12]. However, these methods remain research tools and are not widely available in clinical settings. The Papanicolaou smear has also been examined as a potential tool to diagnose BV because of its widespread use, but reported results have been only fair (sensitivity 32%-55%)[13,14].

Most recently, researchers have adopted the Gram stain of vaginal secretions as the method of choice for BV diagnosis because of its higher reproducibility than the clinically based Amsel criteria. The best Gram method is considered to be that of Nugent et al.[15] This method uses a standardized scoring system ranging from 0-10 points. However, many clinicians have not adopted the Gram stain method for diagnosis of BV because it requires more time to perform and a trained laboratory technician to read the slides. Recently, new methods have been developed to achieve rapid "point of care" diagnosis of BV. These new techniques eliminate the need for microscopy to detect "clue cells" (16), which is time-consuming, and the "Whiff test," which is a subjective assessment for the presence of amines by the clinician.

Because of the evolving importance of BV to women's reproductive health and new diagnostic tools becoming available to the practitioner, we undertook this study to:

(1) determine the prevalence of BV by Gram stain (Nugent criteria) in a healthy, asymptomatic, non-pregnant, non-clinic sample of both sexually experienced and inexperienced young women from throughout the U.S.;

(2) identify sociodemographic factors (race/ethnicity) and clinical factors (sexual behavior, contraception, current/past STDs) associated with a BV diagnosis; and

(3) assess the performance of a rapid colorimetric pH test card and the Papanicolaou smear as screening methods for BV compared to Gram stain.

MATERIALS AND METHODS

Sample: This study represents the baseline clinical data collected from women recruits participating in a larger longitudinal intervention study to prevent STDs and unintended pregnancy. All females who entered recruit training for the United States Marine Corps between

June 1999 and June 2000 and completed the required routine pelvic examination with STD screening and a Papanicolaou smear within two weeks of arrival were eligible for participation in the study.

Procedures:

Consent: Voluntary, written, informed consent to participate in the study was obtained by female civilian research assistants prior to data collection. Women were free to decline participation and were not penalized in any manner if they did so. The institutional review boards of the University of California, San Francisco and the Beaufort Naval Hospital in South Carolina approved the protocol.

History: The participants reported their reproductive health history including STD history and current gynecological symptoms on a standard clinic form before undergoing a pelvic examination in the Well Women's Clinic. Sexual experience was defined for the purposes of this study as having had vaginal intercourse at least once.

Collection of FVU (first void urine) and self-collected vaginal swabs: Participants received specific instructions from research assistants on the proper collection of the FVU (first 20cc in marked cup) and three self-collected vaginal swabs (Insert each swab 1-2 inches, rotate swab around in vagina three times, and place in plastic transport tube). One cotton swab was used for *T. vaginalis* detection. One of the dacron swabs was used for BV Gram stain analysis and colorimetric pH testing. The other dacron swab was used for LCx™ testing for *C. trachomatis* and *N. gonorrhoeae*. The vaginal samples were transported to the clinic's laboratory within five minutes of collection. Vaginal and FVU samples targeted for identification of *C. trachomatis* and *N. gonorrhoeae* were kept at 4° C immediately after collection in the clinic and frozen at –70° C in the hospital freezer within 24 hours of collection. They were shipped overnight air freight to

the to the laboratory based at San Francisco General Hospital (author J.S., laboratory director) in batches, maintaining the cold chain with specialized shipping containers using dry ice.

Collection of cervical samples: During the routine pelvic examination, endocervical samples were obtained for *C. trachomatis* and *N. gonorrhoeae* using the LCx™ kit swabs according to the manufacturer's directions and endocervical samples for Papanicolaou smears were obtained using a cytobrush applied to a glass slide and fixed with a preservative spray. After the clinician collected the endocervical swabs, specimens were transported maintaining the cold chain to the Navy Hospital.

Laboratory Tests:

1) *C. trachomatis* and *N. gonorrhoeae:* Vaginal, FVU and endocervical samples were processed according to manufacturer's directions for ligase chain reaction (LCR) tests (LCx™, Abbott Laboratories, Abbott Park, Ill.). A positive on any of the samples (vaginal, FVU or endocervical) was considered positive for infection with the respective organism for our analysis purposes.

2) *T. vaginalis*: The second self-collected vaginal swab was tested for *T. vaginalis* using the Trichomonas In-Pouch TV (Biomed Diagnostics, San Jose, California) according to the manufacturer's instructions. They were incubated in pouches at collection at 37° C and read for the presence of *T. vaginalis* at two and five days of inoculation by trained research assistants.

3) Gram stain diagnosis of BV using the Nugent criteria: Within five minutes of the self-collection, the vaginal swabs were rolled onto glass slides. The slides were then air-dried, stored, and then transported in batches by overnight air freight on a monthly basis to the laboratory based at San Francisco General Hospital (J. Schachter, Ph.D., laboratory director). The slides were Gram-stained and evaluated by a trained laboratory technologist (author JM). The Nugent

criteria score vaginal flora as normal (0-3), intermediate (4-6) and positive (7-10) for BV.[15] Only Gram stains with Nugent scores of 7-10 were considered positive for BV.

4) Vaginal pH: (FemExam® pH and Amine TestCard™, Litmus Concepts, Inc, Santa Clara, CA, USA): After the self-collected swab was applied to a glass slide (for BV), the swab was then applied to the FemExam® test card to detect elevated pH, according to the manufacturer's directions. If the pH>4.6, the pH test area shows a blue "+" sign. Readings were performed in the clinic's laboratory by a trained research laboratory technician, who was unaware of the woman's history and the clinician's findings on examination. (The amine portion of test card was not included in analysis because the test could not be performed according to manufacturer's directions, i.e. immediately at bedside.)

5) Papanicolaou examination: At the Beaufort Naval Hospital's regional laboratory, one cytopathologist reviewed the slides according to standard Bethesda criteria[16] and was unaware of the woman's presence or absence of vaginal symptoms and the purpose of the study. Papanicolaou diagnoses consistent with BV were defined as a report specifying "clue cells and/or non-specific vaginitis."

Statistical analyses: The associations between Gram stain diagnoses of BV and race/ethnicity, contraceptive use, history of sexually transmitted infections, and history of sexual activity were examined using Chi-Square and Fisher's exact tests where applicable. The sensitivity, specificity, and positive and negative predictive values of the pH colorimetric test and Papanicolaou smears were determined using the Nugent criteria as the diagnostic standard.

To investigate differences in BV prevalence by race/ethnicity [(e.g., in Asian/Pacific-Islanders (APIs)] in greater detail, we performed subgroup analyses among the sexually experienced women examining BV prevalence by ethnicity using Chi-square test. We then

performed post-hoc t-tests with Bonferroni correction comparing each of the ethnicities to each other e.g. API vs. African Americans, Caucasians vs. Native Americans, etc. Then we repeated this in only the non sexually experienced and then in only those negative for all three STDs.

RESULTS

Of the 2157 participants (94% of those who were approached), 1938 had complete data for assessment of BV using the Nugent criteria; 1652 had complete data for analysis of colorimetric test card performance (samples were excluded if there was blood on the swab which made the results invalid); and 1858 had complete data for Papanicolaou performance analysis.

Selected demographic and clinical characteristics of the study sample are shown in Table 1. The study participants were on average 19.1 years old (SD = 2.1 years, range 17-33 years) with 75% between ages 17-19 years. In addition, they were ethnically/racially diverse, and most had experienced vaginal sexual intercourse in their lifetime (86%). Of the participants, 19% reported vaginal discharge and 6.6% reported vaginal odor. Findings consistent with BV were reported on 35% of Papanicolaou smears. Of the sexually experienced participants, 11.4% were infected with *C. trachomatis,* 2.3% with *N. gonorrhoeae*, and 1.7% with *T. vaginalis*.

Prevalence of BV by sexual experience and race/ethnicity. The overall prevalence of BV by the Nugent criteria was 27% (516/1938) with differences in rates by sexual experience: 28% (468/1675) among the sexually experienced and 18% (48/263) among the non-sexually experienced (p=.001). BV prevalence also differed by race/ethnicity: 25% in Caucasians, 32% in African-Americans, 30% in Hispanic/Latinas, 34% in Native Americans, 11% in Asian/Pacific Islanders, and 26% in other groups. The lower BV prevalence in Asian/Pacific Islanders was statistically significantly different when compared to any of the other ethnic groups ($X^2 = 17.199$, p=.004).

Clinical factors associated with BV diagnosis. BV was positively related to self-report of vaginal discharge (p=.001) and self-report of vaginal odor (p<.001) (Table 2). Among those sexually experienced, *C. trachomatis* (p=.002) infection was found to be associated with BV. In contrast, there was an inverse relationship between a BV diagnosis and report of hormonal contraceptive use (p=.013) (Table 3). BV was not associated with prior STD history, having more than one sexual partner in the past three months, barrier contraception use, clinician detection of vaginal discharge, nor current *T. vaginalis* or *N. gonorrhoeae* infections.

Performance profiles of the pH colorimetric test and Papanicolaou smear. The sensitivity/specificity of a positive pH test were 72%/67% respectively. The performance of the Papanicolaou smear yielded a sensitivity of 72% and a specificity of 79% for detection of BV using the Nugent criteria as the standard.

Analyses to explore the lower BV prevalence in Asian/Pacific Islanders (APIs). We examined if the lower BV prevalence in APIs compared to the other groups was associated with a number of key factors, including sexual experience, OCP use, number of sexual partners, and STD status. Specifically,APIs compared to other groups did not differ by OCP use or number of sex partners in the past 3 months(p = .07-.91 and p =.30-.98, respectively). Analysis of BV prevalence by race/ethnicity showed a significantly lower BV prevalence in APIs compared to other ethnicities in three subgroups:those sexually experienced, p=.04; those non-sexually experienced, p=.018; and those who were negative for all three STDs examined, p=.039.

DISCUSSION

The prevalence of BV among a healthy, racially/ethnically diverse sample of young women from throughout the United States using Nugent's criteria was found to be 27%, with a significantly higher rate among the sexually experienced (28%) compared to those without

sexual experience (18%). This confirms previous research that showed a significant positive relationship between sexual experience and the presence of microbes associated with BV.[17] Women entering the military represent a unique diverse national sample to study, when compared to previous BV research that has focused largely on women attending gynecology, prenatal, and STD clinics.[9, 10, 17-20] When compared to other studies using the Nugent Criteria, our overall BV prevalence rate was higher than the 7% prevalence found in asymptomatic general practice patients[9] and more consistent with samples of women attending family planning[19] and STD clinics.[20]

Our sample of 263 of young women who report never experiencing vaginal intercourse is the largest sample of non sexually experienced women published to date which determined BV prevalence using the Nugent criteria. Previous smaller studies of non-sexually experienced young women and girls using Amsel's criteria showed prevalences ranging from 0% (n=18)[11] to 12% (n=52).[21] Our higher prevalence in both the sexually experienced and non-sexually experienced women are most likely due to our use of the Nugent criteria for diagnosis which is more sensitive than the clinically based Amsel's criteria. Previous studies have shown that Amsel's criteria have a sensitivity of only 35-56% and specificity of 96-99% when compared to the Nugent criteria.[17, 22] It is also possible that the young women underreported prior sexual experience if such activity was involuntary or not heterosexual. Finally, our reported BV prevalence among the sexually experienced cohort is consistent with previous studies that used the Nugent criteria.[19, 20, 22, 23]

Given our large sample, we were able to examine BV prevalence by race/ethnicity and found a statistically significantly lower rate among Asian/Pacific Islanders compared to all other groups. Although BV is not an exclusively sexually transmitted infection, these findings follow

the pattern of infection for a number of STDs. However, the lower prevalence in Asian/Pacific Islanders remained significant when we looked at only those that were negative for all three STDs and only those that were non-sexually experienced. Perhaps the difference in prevalence by ethnicity could be explained by differences in douching practices (which has been associated with BV[19]) or foreign body use (e.g. tampons,[19] sex toys, etc.) that might affect the vaginal ecosystem, as well as other factors which may vary by ethnicity that we did not examine in this study. More detailed studies on factors associated with BV in diverse ethnic/racial groups are clearly warranted.

Frequently, clinicians diagnose vaginal infections by syndromic diagnosis, relying mainly on history and the observation of discharge.[24] Clinicians are accustomed to investigating vaginal discharge, but our findings of the association of BV and "self-reported" vaginal odor adds another symptom for which clinicians can query their patients. Our findings also support the use of pH to assist in the diagnosis of BV for clinicians without access to microscopy given its reasonable sensitivity (72%) but keeping in mind its lower specificity (67%), when compared to the Gram stain as the gold standard for diagnosis. The Papanicolaou smear may prove to be useful under some circumstances to screen for BV. We found the sensitivity and specificity for the Papanicolaou smear (70%/79%) to be comparable to and consistent with previous studies reporting sensitivities ranging from 55% to 89% and specificities from 85% to 96%.[14, 22] If BV is determined to pose a significant morbidity for non-pregnant women, the Papanicolaou smear may be a reasonable "first-line" screening tool during routine gynecological exams of healthy populations given its moderate performance and that it adds no cost to the routine pelvic examination of adult women.

Finally, regarding clinical correlates of BV, our finding of an increased prevalence of BV among those women with *C. trachomatis* infection is supported by other research,[25] which suggest that BV may facilitate STD infection by decreasing local secretory leukocyte protease inhibitor levels. Although we did not find an association between *N. gonorrhoeae* and *T. vaginalis* infection and BV, this may be due to the low number of positives (39 and 28 respectively), given that the difference in BV prevalence was the same as that with *C. trachomatis* infection. Furthermore, our finding showing an association between hormonal contraception and BV, suggesting a possible protective factor against BV, has been described by other groups as well.[19, 26-30] Given that our study is cross-sectional, no causal relationship can be determined. Further research is indicated to explain the associations between BV and both *C. trachomatis* and hormonal contraception.

In summary, BV is prevalent in young women who have and have not experienced vaginal intercourse and varies by race/ethnicity. The Papanicolaou smear and pH testing performed moderately well as screening tests for BV. Lastly, this study reinforces the need for more research on the inverse relationship between BV and hormonal contraceptive use and the direct relationship between BV and *C. trachomatis* infection.

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Table 1. Characteristics of 1938 women

Age (years)	
Mean (range=17-33 years)	19
	N (%)
Race/ethnicity	
Caucasian	1092 (56.3)
Hispanic	387 (20.0)
African-American	306 (15.8)
Asian/Pacific Islander	63 (3.3)
Native American	44 (2.3)
Other/mixed	46 (2.4)
Ever had vaginal intercourse	1675 (86.4)
Self-report vaginal discharge	374 (19.4)
Self-report vaginal odor	127 (6.6)
Clinician detected vaginal discharge	100 (5.3)
BV changes on Papanicolau Smear	641 (34.6)

Table 2. Relationship of Nugent (+) with history and exam in all women

	Answered Yes		Answered No		
	Nugent (+)/ n	%	Nugent (+)/ n	%	p
Ever had vaginal sex	468/1675	27.9	48/263	18.3	**.001**
Self-report vaginal discharge	125/374	33.4	391/1557	25.1	**.001**
Self-report vaginal odor	52/127	40.9	464/1804	25.7	**<.001**
Clinician detected vaginal discharge	31/100	31.0	481/1809	26.6	.354

Table 3. Relationship of Nugent (+) with history and STD status among sexually active women

	Answered Yes		Answered No		
	Nugent (+)/ n	%	Nugent (+)/ n	%	p
Prior STD history	49/144	34.0	414/1500	27.6	.120
> 1 partner in past 3 months	132/411	32.1	268/982	27.3	.069
Hormonal contraceptive- usually	178/714	24.9	283/924	30.6	**.013**
Barrier contraceptive - usually	333/1195	27.9	128/443	28.9	.711
	Positive		Negative		
	Nugent (+)/ n	%	Nugent (+)/ n	%	p
Chlamydia trachomatis	72/191	37.7	396/1483	26.7	**.002**
Neisseria gonorrhoeae	14/39	35.9	454/1181	27.8	.280
Trichomonas vaginalis	10/28	35.7	458/1643	27.9	.285

* Some denominators vary because of missing data on some variables

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Appendix 1.d.

Boyer CB, Shafer MA, Moncada J, Schachter J, Shaffer RA, Brodine SK: Sociodemographic, behavioral, and clinical factors associated with STDs in a national sample of women entering the US military. *ISSTDR: Sexually Transmitted Infections* 241-246, 2001.

Sociodemographic, Behavioral, and Clinical Factors Associated With STDs in a National Sample of Women Entering the US Military

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Summary

STDs are epidemic among sexually active young women in the U.S.[1,2] Although research exists linking risk factors to STDs in young women, most studies were conducted in clinic-based samples of women seeking reproductive health care.[3,4,5] The purpose of this study was to determine the role of sociodemographic risk markers, behavioral risk, and clinical factors to acquisition of STDs in women from throughout the U.S. entering military recruit training. Risk factors (in the 3 months prior to the study) that were significantly associated with acquisition of STDs included age, geographic location of residence, race/ethnicity of the most recent sexual partner, inconsistent use of birth control, and vaginal symptoms. The high prevalence rates of STDs in this national, non-clinical sample of young women suggest the need for ongoing prevention interventions including STD screening and behavioral risk reduction programs that target non-college students.

Introduction

Sexually experienced women, ages 15-24 years, have higher rates of chlamydia (CT) and gonorrhea (GC) than any other age group.[1] These infections pose serious health concerns for young women because of their association with adverse reproductive health outcomes such as pelvic inflammatory disease, tubal infertility, ectopic pregnancy, and increased risk of exposure to HIV.[1,2] The risk of exposure to STDs is the result of complex interrelationships among sociodemographic risk markers and behavioral risk factors. Much of what is known about these factors is reported from STD and family planning clinics.[3,4,5] These data may overestimate the prevalence of STDs in young women. Women entering recruit training for military service represents a more ideal national, non-clinical cross-section to assess the prevalence of STDs in this group.

Methods

Procedures

All women recruits (N= 2288) between June 1999 and June 2000 were approached to participate in the study. A total of 2157 (95%) women voluntarily agreed to participate either in a cognitive-behavioral, skills-building intervention to prevent unplanned pregnancies and STDs or a nutrition and fitness program. Assignments to the programs were random. At baseline, prior to the intervention, the participants completed a self-administered questionnaire and were screened for asymptomatic CT, GC, and trichomonas vaginalis (TV).

Questionnaire

The questionnaire included queries on sociodemographic risk markers (age, race/ethnicity, marital status, education, geographic residence, sexual partner's age and race/ethnicity); behavioral risk in 3 months prior to the survey (number of primary and casual sexual partners, frequency of birth control use, condom use, alcohol/substance use, sex under the influence of alcohol/substance use, perceived STD risk of sexual partners; and clinical risk factors (history of pregnancy, STDs, and vaginal symptoms at screening).

STD Screening

C. trachomatis and *N. gonorrhoeae* were tested applying LCx™ to FVU samples and self-administered vaginal swabs. Specimens were frozen to –70°C within 24 hours of collection and transported to an author's research laboratory (Schachter) while maintaining the cold chain. Specimens were processed as previously described.[6] A self-administered vaginal swab for *T. vaginalis* was immediately inoculated into the In-Pouch TV™ (Biomed Laboratories) and read at 2 and 5 days.

Data Analyses

All statistical analyses were performed using data from study participants who self-reported as having had sexual intercourse (n=1826). Conventional descriptive statistics were used to assess the characteristics of the participants. Bivariate comparisons between participants who were STD positive and STD negative were made using X^2 test of differences in proportions. To determine the best model for predicting an STD diagnosis, the variables (based on the prior 3 months) that were significantly associated with diagnosis of an STD at the bivariate level ($p \leq .10$) were entered into a logistic regression equation then subjected to a backward stepwise procedure, using an iterative process. Criterion for retention in the model was a likelihood ratio test with a p-value ≤ 0.05.

Results

The participants were young women (mean age = 19.2 years) of diverse racial/ethnic background (58% Caucasian, 20% Latina, 17% African American, 6% Other) who were largely from urban settings (78%). These women were primarily single (92%), sexually experienced (85%) and at risk for STDs; 16% had a history of pregnancy and 11% had a history of STDs. In the 3 months prior to the study, 12% had ≥2 primary partners, 11% had ≥2 casual partners, 57% used alcohol/substances before/during sex, 39% rarely or never used birth control and 73% did not use condoms consistently; 18% perceived their partners had other partners. At screening, 24% had vaginal symptoms, and 13% were positive for an STD (11% *C. trachomatis*, 2% *N. gonorrhoeae*, 2% *T. vaginalis*).

Conclusions

This cohort of young women entering the military commonly reported

Table 1. Bivariate Associations Between Sociodemographic, Behavioral, and Clinical Factors with STD Diagnosis

Risk Variable	3-Month Model X^2
Age	6.92*
Race/Ethnicity	63.76***
Marital Status	2.79#
Education	0.00
Geographic Location	3.89*
Sexual Partner's Age	1.91
Sexual Partner's Race	87.30***
Sexual Partners	4.32*
Casual Partners	0.52
Birth Control Use	8.78*
Condom Use	2.39
Heavy Alcohol Use	1.17
Substance Use	1.26
Sex Under the Influence Of Alcohol/Substances	1.74
Perception that Sex Partner Had Other Partners	9.32**
Perception that Sex Partner Had STDs	5.14*

***p<0.001; **p<0.01; *p<0.05

Table 2. Significant Factors Associated with an STD Diagnosis: A 3-Month Model

Variable	Odds Ratio	95% C.I.
Age (19-20)^		
17-18 years	1.53	1.05-2.23
21+	1.97	1.21-3.21
Geographic Residence (Urban)^		
Rural	1.61	1.12-2.32
Race/Ethnicity Last Sex Partner (Caucasian)^		
Latino	1.47	0.94-2.33
African Americans	4.73	3.29-6.79
Asian/PI	2.02	0.44-9.30
Native American	2.20	0.87-5.60
Birth Control Use (Usually/Always)^		
Never/Almost Never	1.25	0.88-1.78
Sometimes	1.99	1.21-3.26
Perception that Sex Partner Had Other Partners (No)^		
Yes/Possible	1.40	1.02-1.93
Vaginal Symptoms At Screening (No)^		
Yes	1.50	1.07-2.11

^Reference Group

risky sexual behaviors. A high prevalence of STDs (CT, GC, TV) was diagnosed among these women, including 76% asymptomatic infections. The risk factors associated with STD infections identified in this study are consistent with those reported in the current literature.[3,4,5] The 3-month STD risk model provide insight into factors that place these young women at risk for STDs including having an African American sexual partner, having the perception that their sexual partner have/may have other concurrent sexual partners, and inconsistently using birth control. Our findings on the association of African American race and STDs are consistent with current national surveillance data on STDs.[1] Recent research suggest that African Americans' increased risk of STDs may be, in part, related to a higher prevalence of STDs among their sexual partners who are older and at higher risk, and who may be a part of geographic "core groups" within which there is a high prevalence of STDs.[7] Many of these young women are engaging in risky sexual behaviors that may lead to major STD-related reproductive morbidity such as ectopic pregnancy and infertility. Ongoing STD prevention interventions are needed to address risk factors that are amenable to change such as choice of sexual partners, use of effective birth control, and seeking appropriate reproductive health care, especially for detection and treatment of asymptomatic STDs.

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Appendix 2.

Brief, 2003

Presented to Presented to Lt. Colonel Johnson and Colonel Bearor, at Marine Corps Recruiting Depot, Parris Island, SC.

Preventing STDS and Unplanned Pregnancies: A Cognitive-Behavioral Intervention for Marine Corps Female Recruits

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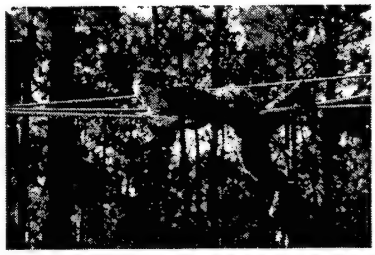
Fort Detrick, MD

FOCUS

...on the choices you make now
that will effect your future and career

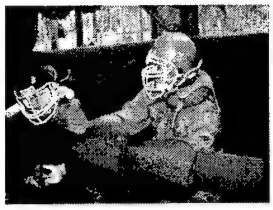


Background

- Sexually experienced women, ages 15-24 years, have the highest rates of chlamydia and gonorrhea.
- These infections pose serious health concerns because of their association with pelvic inflammatory disease, tubal infertility, ectopic pregnancy, and HIV.
- The risk of STDs is the result of complex interrelationships among sociodemographic and behavioral risk factors.

Background

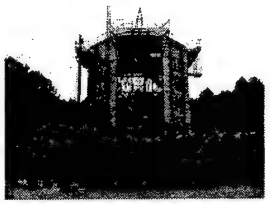
- Little is known about the risk and prevention of STDs and unplanned pregnancies in healthy, non-clinic samples of women.
- Military training, with defined opportunities for risk, is an ideal setting for evaluating prevention interventions in young women.



Until now, the military has taught only two methods of contraception...

Overall Goal

To prevent unplanned pregnancies and STDs in women entering recruit training for the U.S. Marine Corps.



Methods

- All women (N= 2288) enrolled in recruit training at the United States Marine Corps Recruiting Depot between June 1999 and June 2000 were recruited to the study.
- 2157 (94%) of women volunteered to participate in a cognitive-behavioral, skills-building intervention to prevent unplanned pregnancies and STDs or a nutrition and fitness intervention.

Methods
(continued)

- Assignment to the interventions was randomized by platoons.
- The participants completed self-administered questionnaires and were screened for *C. trachomatis, N. gonorrhoeae,* and *T. vaginalis* at three assessments.

Study Design

Baseline T1	MCT Initial Follow – up T2 4 weeks	First Duty Assignment Second Follow-up T3 12 months
Questionnaire STD Screen Interventions "FOCUS" "Fitness for Life"	Questionnaire STD/Pregnancy Screen	Questionnaire STD/Pregnancy Screen

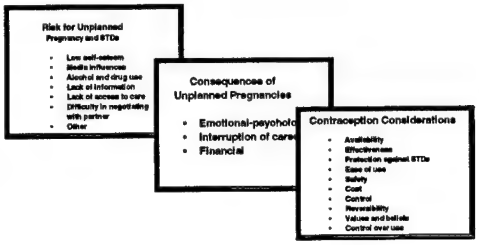
"FOCUS" Curriculum Goals

- Educate about the risk and impact of unplanned pregnancies, STDs and HIV.
- Provide factual information on effective methods of contraception and STD prevention.
- Describe the basics of a GYN exam and female reproductive anatomy.

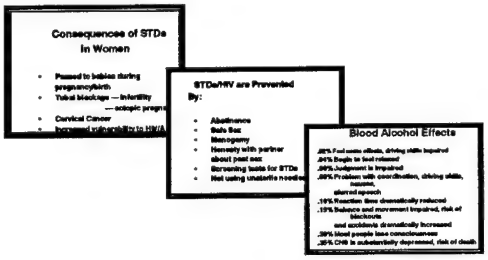
"FOCUS" Curriculum Goals
(continued)

- Build communication and decision-making skills regarding sexual behaviors and use of contraception.
- Provide information about the effects of alcohol use on sexual risk behaviors.

"FOCUS"
EXAMPLES OF DIDACTIC INFORMATION



"FOCUS"
EXAMPLES OF DIDACTIC INFORMATION



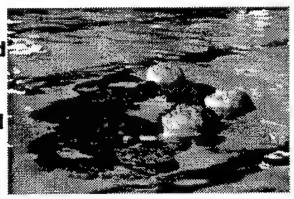
"FOCUS"
EXAMPLE OF A ROLE-PLAY EXERCISE

"Let's talk about sex and contraception"

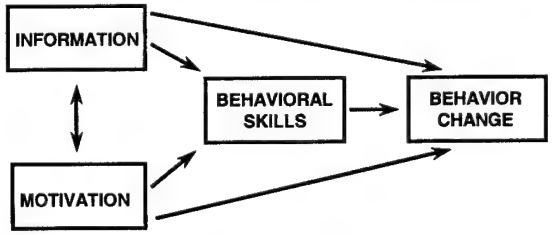
"Imagine that you are in the beginning weeks of a new relationship. You really like this guy a lot and think this relationship has the potential to develop into something special. But you want it to be different than previous relationships. You've promised yourself that in any new relationship you will start off by being open and honest in talking about sex before you're in the heat of the moment. You also realize that beginning the conversation is difficult and a little scary. What do you say?"

"FITNESS FOR LIFE" CURRICULUM GOALS

- Improve participants' physical performance through healthier food choices.
- Reduce participants' risk of sports/physical training injuries.
- Examine the risk and prevention of cervical and breast cancer.



Theoretical Framework
Information-Motivation-Behavioral Skills Model

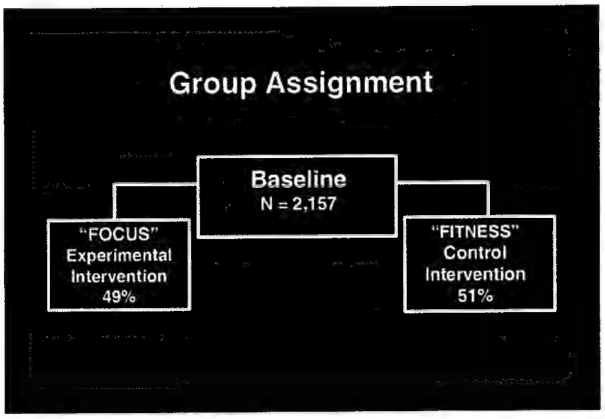


Fisher & Fisher, 1992; 1996

Intervention Strategies

Approach
- Didactic Slides
- Interactive Group Exercises
- Military-Specific Videos

Format
- Small Groups (20-25)
- 4, Two-hour Sessions



Baseline Characteristics

Age	
17-18	54%
19-20	31%
≥ 21	15%
Race/Ethnicity	
Caucasian	56%
Latina	20%
African American	16%
Asian/PI/Native American	8%

Baseline Characteristics

Marital Status	
Married	8%
Single	92%
Geographical Location of Residence	
Urban	78%
Rural	22%

Baseline Sexual Behaviors

Sexual Partners	
1	18%
≥ 2	82%
Casual Partners	
≥1	65%
Frequency of Birth Control	
Never/Sometimes	33%
Usually/Always	67%
Condom Use	
< 100%	78%

Baseline STD Prevalence

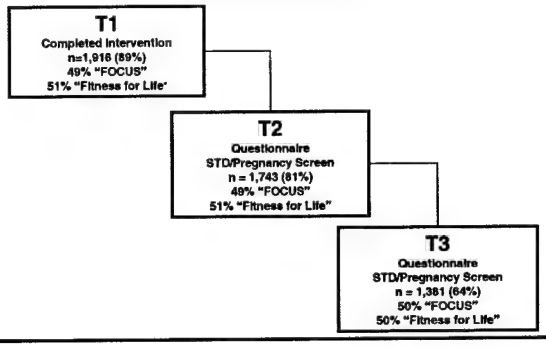
Any Positive	14%
C. trachomatis*	11%
N. gonorrhoeae*	2%
T. vaginalis**	2%

* by LCx[R]
** by Trich-In-Pouch[R] (self-swab)

Baseline Sexual History Categories

NSE (Safe) (15.6%)	Not sexually experienced
No HX (Safe) (20.4%)	Sexually experienced but no hx pregnancy/STDs ~AND~ 1 partner and 100% condom use
No Hx (Unsafe) (31.7%)	Sexually experienced but no hx pregnancy/STDs ~AND~ ≥2 sex partners or < 100% condom use
HX (32.3%)	Had hx pregnancy/STDs

Assessments



Post Intervention STD Acquisition

Any Positive	**15%**
C. trachomatis*	**12%**
N. gonorrhoeae*	**1%**
T. vaginalis*	**1%**

* by LCx®
** by Trich-In-Pouch® (self-swab)

Post Intervention Sexual Behaviors

Unplanned Pregnancy	**7%**
Multiple Sexual Partners	**57%**
Casual Sexual Partners	**43%**

Effect of FOCUS Intervention
Unplanned Pregnancy or STD Acquisition

% Positive		
Fitness	**Focus**	**Odds Ratio#**
24%	**18%**	**1.41***

*p< 0.05
#Adjusted for history of STDs, pregnancy, sexual history, latency, and clustering effects by platoon

Effect of FOCUS Intervention
STD Acquisition

	% Positive		
Sexual History	**Fitness**	**Focus**	**Odds Ratio#**
NSE	16%	10%	1.68
No Hx (Safe)	10%	11%	0.89
No Hx (Unsafe)	**22%**	**8%**	**3.24*****
Hx (STDs/Pregnancy)	18%	19%	0.96

*** p< 0.001
#Adjusted for latency and clustering effects by platoon

Effect of FOCUS Intervention

Multiple Sexual Partners

Sexual History	% Positive Fitness	% Positive Focus	Odds Ratio#
NSE	35%	26%	1.87*
No Hx (Safe)	60%	55%	1.45
No Hx (Unsafe)	60%	71%	0.70
Hx (STDs/Pregnancy)	56%	60%	0.93

*p< 0.05
#Adjusted for group, latency, and clustering effects by platoon

Effect of FOCUS Intervention

Casual Sexual Partners

Sexual History	% Positive Fitness	% Positive Focus	Odds Ratio#
NSE	31%	18%	2.05*
No Hx (Safe)	43%	40%	1.11
No Hx (Unsafe)	46%	55%	0.69
Hx (STDs/Pregnancy)	43%	44%	0.93

*p< 0.05
#Adjusted for group, latency and clustering effects by platoon

Summary

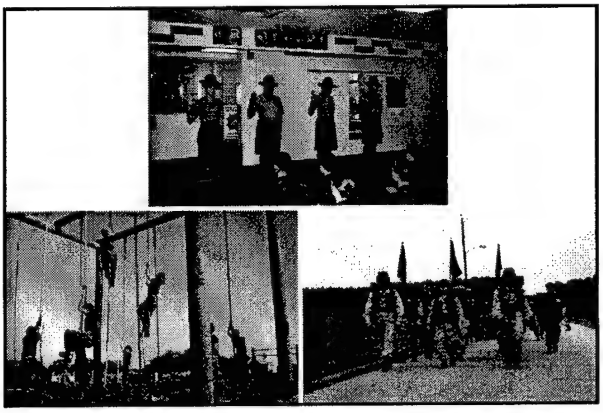
- Women participating in the FOCUS intervention were less likely to have an unplanned pregnancy or an STD.
- The FOCUS intervention's effect differed by participants' level of sexual history.
- The FOCUS intervention had the most salient impact on reducing STDs in women who, at baseline, had multiple sexual partners or used condoms inconsistently.

Summary

- Women participating in the FOCUS intervention, who were not sexually experienced at baseline, were less likely to engage in sex with multiple or casual partners when they initiated sex.
- These findings suggest that future interventions may need to consider other factors in order to have an impact on women in other risk categories.

Conclusions

- The high prevalence of sexual risk and STDs in this national, non-clinical sample of young women suggests the need for ongoing reproductive health interventions for young women post high school.
- The findings of this randomized controlled trial indicate that cognitive-behavioral skills-building interventions are both feasible and effective strategies to reduce behavioral risk and prevent STDs and unplanned pregnancies in young at risk Marine Corps female recruits.



Appendix 3

Abstracts

a. Shafer MA, Boyer CB, Pang F, Moncada J, Dubovtsev A, Brodine S, Shaffer R, Schachter J. Comparison of 3 Specimen Collection Techniques – Endocervical and Self-administered Vaginal Swab to Screen for *C. trachomatis* (CT) and *N. gonorrhoeae* (GC) by NAATS in Women Marine Recruits. IV European Chlamydia Congress, Chlamydia 2000, Helsinki, Finland, August 2000.

b. Boyer CB, Shafer MA, Pollack L, Kraft H. Sexually Transmitted Disease Acquisition in a National, Non-Clinical, Diverse Sample of Young Women: Associations of Sociodemographic, Behavioral, and Clinical Factors. Proceedings of The Society of Behavioral Medicine's 22nd Annual Meeting, Seattle, Washington, March 21-24, 2001.

c. Boyer CB, Shafer MA, Betsinger K, Shaffer RA, Brodine SK, Kraft H, Schachter J: Preventing HIV, STDs, and Unplanned Pregnancies in Young Women Entering the US Military: A Cognitive-Behavioral Approach. 2001 National HIV Prevention Conference, Atlanta, Georgia, August 12-15, 2001.

d. Boyer CB, Shafer MA: Development of a Cognitive-behavioral Group Randomized Control Intervention Trial to Prevent STDs and Unplanned Pregnancies for Young Women Entering the US Military. *Journal of Adolescent Health,* 30(2):129, 2002.

e. Yen S, Shafer MA, Moncada J, Campbell HC, Henry LC, Flinn K, Flinn S, Boyer CB. How Common is Bacterial Vaginosis (BV) and How Good are the Tests: Comparing FemExam(R) PH, Amine Testcard and Papanicolaou Smear to Nugent's Criteria in a Non-clinic Population of Young Female Military Recruits. *Journal of Adolescent Health*, 30(2): 97-98, 2002

f. Boyer CB, Shafer MA. Preventing STDs and Unplanned Pregnancies: A Cognitive-Behavioral Intervention for Young Women Entering the Military. *Journal of Adolescent Health*, 32(2):129, 2003.

g. Yen S, Shafer MA, Moncada J, Boyer, CB. Prevalence of Bacterial Vaginosis by Nugent's Criteria in a Non-Clinic Sample of Young Women Entering the Military: Relationships with Sexual Experience, Vaginal Symptoms and Signs. *Journal of Adolescent Health*, 32(2):128, 2003.

h. Boyer CB, Shafer MA, Schachter J, Shaffer RA, Pollack LM, Chang Y, Brodine S. Preventing STDs and Unplanned Pregnancy in a National, Non-Clinical Sample of Young Women: A Cognitive-Behavioral, Group, Randomized Controlled Intervention Trial For Military Recruits. Presented at the 2003 ISSTDR Congress, Ottawa, Canada, July 27-30, 2003.

i. Shafer MA, Boyer CB, Schachter J, Moncada J, Pollack LM, Chang Y, Shaffer RA. Predicting Acquisition of *C. Trachomatis*, *N. Gonorrhoeae*, and *T. Vaginalis* in a Non-Clinical National Sample of Young Military Women During Their First Year of Service. Presented at the 2003 ISSTDR Congress, Ottawa, Canada, July 27-30, 2003.

Official Abstract Form

COMPARISON OF 3 SPECIMEN COLLECTION TECHNIQUES-ENDOCERVICAL, FIRST CATCH URINE AND SELF-ADMINISTERED VAGINAL SWAB TO SCREEN FOR *C.TRACHOMATIS* (CT) AND *N.GONORRHOEAE* (GC) BY NAATS IN WOMEN MARINE RECRUITS.

MA Shafer[1], C Boyer[1], F Pang,[2], J Moncada[2], A Dubovtsev[1], S Brodine[3], R Shaffer[3], J Schachter[2]
University of California, San Francisco, Departments of Pediatrics[1] and Laboratory Medicine[2]; Naval Health Research Center, San Diego, CA[3].

Objective: To determine the performance profile of 3 specimen collection methods to detect CT and GC by NAATs applied to endocervical (Cx), first catch urine (FCU) and self-administered vaginal swab (Vag) specimens in women Marine recruits.
Methods: At entry into the military, all women Marine recruits are screened for cervical CT and GC using LCx^R (Abbott) and have Pap smears taken during routine pelvic exams which are processed by a military contract laboratory. To date, 1110 women have voluntarily consented to participate in a behavioral intervention to prevent STD acquisition and unintended pregnancy; 6% refused participation. All participants completed a self-report survey and provided a FCU and 3 self-administered vaginal swabs for screening for CT and GC using LCx^R (Abbott). An additional vaginal swab was obtained for *T.vaginalis* (TV) culture (*Trich In- Pouch^R*).
Results: Analyses were based on 796 sexually experienced women who had all 3 specimens tested. Ss had a mean age of 18.8 years, were ethnically diverse (55% W, 21% H, 17% Af Am, 7% As/Other), and largely never-married (92%). 13% reported a history of pregnancy and 8% reported a history of an STD(s). In the past 3 months, 15% reported sexual activity, and 25% had ≥ 2 partners. Currently,40% used hormonal birth control, 76% used condoms, and 25% complained of genital symptoms on clinical history. 127(16%) of infections were identified: 90(11%) CT, 21(3%) GC, 16 (2%) TV.

Table: Sensitivities for CT and GC by Collection Method (N=796)

C.trachomatis		
Cx 68%	FCU 72%	Vag 88%
Cx+FCU 86%	Vag+FCU 94%	Cx+Vag 97%
N.gonorrhoeae		
Cx 43%	FCU 32%	Vag 81%
Cx+FCU 52%	Vag+FCU 86%	Cx+Vag 100%

Conclusion: STDs are common among young women Marine recruits. Vaginal swabs proved to be the best single method for identifying CT and GC. Urine performed poorly in identifying CT and GC. Combining 2 collection methods improved the sensitivities with the Cx+Vag combination yielding the best results for identifying CT and GC. Consequently, when screening during a pelvic exam, it appears that the simultaneous sampling of the cervix and vagina, e.g., one swab at endocervix followed by a "spiral" sampling technique of the vagina on exiting, would likely identify the most CT and GC infections without increasing clinician time or costs.

Preferred presentation format (please check):

Oral X Poster _____ Topic preference Diagnostics

Name of presenting author: Mary-Ann Shafer, MD

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I hereby authorise the publication of this abstract in the congress proceedings and the title with names of authors in the website.

Sexually transmitted disease acquisition in a national, non-clinical, diverse sample of young women: Associations of sociodemographic, behavioral, and clinical factors

Cherrie B. Boyer, Ph.D.[1,2], Mary-Ann Shafer, M.D.[1,2], Lance Pollack, Ph.D.[1,3], Heidi Kraft, Ph.D.[4]
[1]University of California, San Francisco, [2]Department of Pediatrics, Division of Adolescent Medicine, 3333 California Street, San Francisco, CA 94143-0503;
[3]Center for AIDS Prevention Studies; [4]Naval Health Research Center, San Diego, CA

Purpose: To determine the relationship of sociodemographic risk markers, behavioral risk, and clinical factors to acquisition of sexually transmitted diseases (STDs) in a national sample of women entering recruit training for the military.

Methods: 2,157 women (mean age = 19.2 years) of diverse racial/ethnic background (Caucasian 58%, Latino 20%, African American 16%, Other 6%) voluntarily participated in a cognitive-behavioral intervention to prevent unplanned pregnancies and STDs. At baseline, participants were screened for STDs and completed a self-reported questionnaire to assess sociodemographic risk markers (age, race/ethnicity, marital status, education, sexual partner characteristics), behavioral risk (age of sexual debut, number of sexual partners, casual sex, use of birth control), and clinical factors (history of pregnancy and STDs, STD-related symptoms).

Results: Participants were primarily single (90%), sexually experienced (85%), and at risk for STDs: 82% had ≥ 2 sexual partners, 16% had a history of pregnancy and 12% had STDs. Many participants used alcohol/substances during/before sex (57%), and did not consistently use birth control (56%) or condoms (73%); 48% perceived their partners had other partners and 18% believed their partners had STDs. At screening, 24% had vaginal symptoms, and 13% were positive for an STD (11% chlamydia). Variables assessed in the three months prior to the study that were associated ($p < .10$) with an STD diagnosis at the bivariate level entered into a backward, stepwise logistic regression equation ($p < .05$). The results indicate that age [$\leq$18 years (OR=1.53, CI =1.05-2.24) or $\geq$21 years (OR = 1.81, CI = 1.11-2.95)], partner's race at last sex [African American (OR= 4.44, CI = 3.11-6.34)], perception that their sexual partners had other partners (OR = 1.43, CI =1.04-1.97), birth control (OR = 1.92, CI = 1.17-3.15), and STD-related symptoms at screening (OR = 1.51, CI = 1.07-2.12) were associated with an STD diagnosis.

Conclusions: These findings from a national, non-clinical sample of young, ethnically diverse women suggest the need ongoing prevention interventions, including behavioral risk reduction programs and STD screening which target non-college bound students.

Title: Preventing HIV, STDs, and unplanned pregnancies in young women entering the U.S. Military: A cognitive-behavioral approach

Authors: Boyer, CB[1]; Shafer, MA[1]; Betsinger K[1], Shaffer RA[2]; Brodine SK[2,3], Kraft H[2], Schachter, J[1]
[1]University of California, San Francisco; [2]Naval Health Research Center; [3]San Diego State University

Issues: Young, single, sexually experienced women are at risk for HIV/STDs, and unplanned pregnancies (UIPs). Research has shown that HIV/STD prevention interventions based on cognitive-behavioral principles are effective strategies for building skills and/or modifying behaviors associated with these health outcomes.
Setting: The goal is to evaluate the feasibility and effectiveness of a cognitive-behavioral intervention to prevent and reduce the risk of HIV/STDs and UIPs in young women from throughout the United States entering recruit training for the military.
Project: A randomized control trial assessing pre- and post-intervention measures of sexual behavior, STDs, and UIPs, is utilized to evaluate the intervention. The intervention's development was guided by the Information, Motivation, and Behavioral Skills (IMB) Model (Fisher and Fisher, 1992). It consisted of 4, 2-hour interactive and didactic group sessions that focused on: information about the prevention and risk factors associated with HIV/STDs, and UIPs, female anatomy, effective contraceptive methods, and use of alcohol and other substances; psychosocial factors (motivation) such as peer norms, self-efficacy, behavioral intentions; and skills-building strategies to enhance communication and problem-solving skills. The control condition was conducted in a similar manner and focused on improving the participants' physical performance through promoting healthier food choices and preventing physical training injuries.
Results: Of the 2288 women approached, 2157 (94%) voluntarily agreed to participate; 1062 (49%) and 1095 (51%) were assigned, by platoons (groups of 50-60 women), to the intervention and control conditions, respectively. The participants were primarily young, (mean age=19.2 years), single (90%), of diverse racial/ethnic backgrounds (Caucasian 58%, Latino 20%, African American 16%, Other 6%), and sexually experienced (85%). At baseline, the participants were at risk for STDs: 59% initiated sex at $\leq$16 years of age, 82% had $\geq$ 2 sexual partner; 16% had a history of pregnancy and 12% had STDs. In the three months prior to the study, 29% had $\geq$2 partners, 57% used alcohol/substances before/during sex, 56% did not use birth control, and 73% did not use condoms consistently; 48% perceived their partners had other partners. At screening, 24% had vaginal symptoms and 13% were positive for an STD (11% chlamydia, 2% gonorrhea, 2% trichomonas). To date, we have followed 803 (51% intervention) participants at 9-11 months post intervention. This number reflects 42% of the 1912 individuals who completed the program; 49 (3%) have declined further participation and 95 (5%) have been lost to follow-up.
Lessons Learned: Although it is too soon to evaluate the effectiveness of the intervention, our baseline findings of a high prevalence of sexual risk factors and STDs in this national, non-clinical sample of young women suggest the need for ongoing comprehensive interventions that integrate STDs, HIV, and UIPs into a single program. Such programs should include STD screening and behavioral risk reduction and should also target non-college populations.

Journal of Adolescent Health, 30(2):129, 2002

DEVELOPMENT OF A COGNITIVE-BEHAVIORAL GROUP RANDOMIZED CONTROL INTERVENTION TRIAL TO PREVENT STDS AND UNPLANNED PREGNANCIES FOR YOUNG WOMEN ENTERING THE U.S. MILITARY. Cherrie B. Boyer, Ph.D. and Mary-Ann Shafer, M.D., University of California, San Francisco, Department of Pediatrics, Division of Adolescent Medicine, San Francisco, California.

Purpose: The purpose is to evaluate the feasibility and effectiveness of a cognitive-behavioral intervention to prevent and reduce sexually transmitted diseases (STDs) and unplanned pregnancies (UIPs) in young women from throughout the United States entering recruit training for the military between June 1999-June 2000.

Study Design: A randomized control trial with assessments at baseline, 4-6 weeks, and 9-11 months post intervention.

Participants: Of the 2288 women approached 2157 (95%) voluntarily agreed to participate; 1062 (49%) and 1095 (51%) were assigned, by platoons (groups of 50-60 women), to the intervention and control conditions, respectively.

Interventions: Guided by the Information, Motivation, and Behavioral Skills (IMB) Model, the experimental intervention consisted of 4, 2-hour interactive and didactic group sessions on: information, female anatomy, contraceptive methods, alcohol and other substances, sexual risk behaviors, peer norms, self-efficacy, behavioral intentions, and skills-building strategies to enhance communication and problem-solving skills. The control condition was conducted in a similar manner and focused on improving the participants' physical performance through promoting healthier food choices and preventing physical training injuries.

Outcome Measures: STDs, UIPs and sexual behaviors.

Results: The participants were primarily young, (mean age=19.2 years), single (90%), diverse (Caucasian 58%, Latino 20%, African American 16%, Other 6%), and sexually experienced (85%). At baseline, they were at risk for STDs: 59% initiated sex at $\leq$16 years, 82% had $\geq$ 2 sexual partners, 57% used substances before/during sex, 56% did not use birth control, 73% did not use condoms consistently, 16% had a history of pregnancy, and 12% had a history of STDs; 48% perceived their partners had other partners. At screening, 24% had vaginal symptoms and 13% were positive for $\geq$ 1 STDs (11% *C. trachomatis*, 2% *N. gonorrhoeae*, 2% *T. vaginalis*). To date, we have followed 1,240 (49% intervention) participants at 9-11 months post intervention.

Conclusions: Although it is too soon to evaluate the effectiveness of the intervention, we have demonstrated that an intervention such as this is feasible in this field setting. Our baseline findings of a high prevalence of sexual risk factors and STDs in this national, non-clinical sample of young women suggests the need for ongoing comprehensive prevention interventions that integrate STDs and UIPs into a single program. Such programs should include STD screening and behavioral risk reduction and should target non-college populations.

Journal of Adolescent Health, 30(2): 97-98, 2002

HOW COMMON IS BACTERIAL VAGINOSIS (BV) AND HOW GOOD ARE THE TESTS: COMPARING *FEMEXAM® PH-AMINE TESTCARD*™ AND PAPANICOLAOU SMEAR TO NUGENT'S CRITERIA IN A NON-CLINIC POPULATION OF YOUNG FEMALE MILITARY RECRUITS.

[1]Sophia Yen, M.D., [1]Mary-Ann Shafer, M.D., [2]Jeanne Moncada, MS, [3]HM1 Christopher Campbell, [3]LCDR Charles Henry, [3]Kimberly Flinn, NP, [3]CDR Scott Flinn, [1]Cherrie B. Boyer, Ph.D. [1]Dept. of Pediatrics, [2]Dept of Laboratory Medicine, University of California, San Francisco. CA; [3]Beaufort Naval Hospital, Beaufort, S.C.

Purpose: To determine the prevalence of bacterial vaginosis (BV) by Nugent's Gram stain criteria in an ethnically diverse, non-clinic young female sample; and to determine the sensitivity and specificity of an amine and pH colorimetric test and Papanicolaou smear for the diagnosis of BV compared to Nugent's Gram stain criteria. **Methods**: A cross-sectional study was conducted with 2157 young women entering recruit training for the military representing 95% of those approached. Of these, 1752 had complete clinical data available for analysis (specimens were eliminated if there was blood on a swab). Participants actively consented to participate in a longitudinal intervention to prevent STD acquisition and unintended pregnancy. Data were derived from STD screening performed at baseline. Prior to their routine pelvic exam, the women self-administered two vaginal swabs that were placed in a plastic tube, transported to the research laboratory, and processed within 10 minutes of collection. One swab was placed on the *FemExam® pH and Amine TestCard.*™ The tests were read within 2 minutes of placement for pH and the presence of amines; positive tests were determined by a trained research assistant by colorimetric change on the cards. The second swab was used for Gram stain specimens that were read by a trained laboratory technician who was blinded to clinical findings. A positive test for BV was a Nugent score ≥ 7. Papanicolaou smears were sent routinely to the clinical laboratory to be read. **Results**: 1752 Ss were included in the analysis with a mean age of 18.7 years and ethnicity profile of 54%W, 22% H, 16% Af Am, 12% As/Oth; 86% were sexually active. *Clinical:* At examination, 21% self- reported vaginal discharge, while clinicians reported 6% abnormal discharge and 7% abnormal vaginal odor (not using KOH). *Laboratory:* 29% were BV(+) by Nugent's criteria and 34% had clue cells identified on routine Papanicolau smear. *FemExam®* results showed Ss were 33% pH (+) and 6% amine (+). In addition, BV by Nugent's criteria was significantly related to: a history of sexual activity, presence of clue cells on Papanicolaou smear, and amine (+) and pH (+) by *FemExam®* (all at $p<.0001$). The sensitivity/specificity using Nugent's criteria as the standard were 63%/74% for pH and 13%/96% for amines on *FemExam®,* and 68%/80% for clue cells on Papanicolaou smear cytology. **Conclusion**: BV occurs commonly among young women entering military recruit training. Although highly related to diagnosis by Nugent's criteria, pH (*FemExam®*) and Papanicolaou smear cytology performed moderately well while the amine (*FemExam®*) performed poorly as individual BV diagnostic tools. As the importance of the role of BV in reproductive morbidity in young women becomes more defined, it will become important to continue developing and evaluating simple "bedside" tests.

Journal of Adolescent Health, 32(2):129, 2003

PREVENTING STDS AND UNPLANNED PREGNANCIES: A COGNITIVE-BEHAVIORAL INTERVENTION FOR YOUNG WOMEN ENTERING THE U.S. MILITARY

Cherrie B. Boyer, Ph.D. and Mary-Ann Shafer, M.D., University of California, San Francisco, Department of Pediatrics, Division of Adolescent Medicine, San Francisco, California

Purpose: The purpose is to evaluate the feasibility and effectiveness of a cognitive-behavioral intervention to prevent sexually transmitted diseases (STDs) and unplanned pregnancies (UIPs) in young women from throughout the United States entering military recruit training between June 1999 and June 2000.

Methods: ***Study Design*:** A randomized control trial with assessments at baseline and 9-12 months post intervention. ***Setting*:** U.S. military recruit training center. ***Participants*:** A large, national, non-clinic sample of adolescent and young adult women. 2157 voluntarily agreed to participate (94% consent rate); 1062 (49%) and 1095 (51%) were assigned to intervention and control conditions, respectively. ***Interventions*:** Guided by the Information, Motivation, and Behavioral Skills (IMB) Model, the experimental intervention consisted of 4, 2-hour interactive and didactic group sessions on (small group format): information, reproductive anatomy, contraceptive methods, alcohol/other substances, peer norms, self-efficacy, behavioral intentions, and skills-building strategies to enhance communication and problem-solving skills. The control group condition was conducted in a similar format and focused on improving the participants' physical performance through promoting healthier food choices and preventing physical training injuries. ***Risk Groups:*** For the analysis, women were grouped into 4 risk groups (no, low, moderate, high) using a number of STD risk factors (number of sexual partners, consistency of condom use, and history of pregnancy and/or STDs). ***Outcome Measures*:** STDs, UIPs and sexual behaviors.

Results: The participants were primarily young, (mean age=19.2 years), single (93%), diverse (43% non-Caucasian), sexually experienced (85%) and at risk for STDs: 59% had sex $\leq$16 years, 82% had $\geq$ 2 sexual partners, 57% used substances before/during sex, 56% did not use birth control, 73% used condoms inconsistently, 16% had a history of pregnancy and 12% had STD(s); 48% perceived partners had other partners. At STD screening, 24% had vaginal symptoms and 14% were positive for one or more STDs (11% *C. trachomatis*, 2% *N. gonorrhoeae*, 2% *T. vaginalis*). 1,382 women (72% of those who completed the intervention) were followed 9-12 months post-intervention. Significant group differences were found among a sub-group of the women at follow-up. Specifically, women who were categorized, at baseline, to be at 'moderate risk' (reported multiple sexual partners, inconsistent condom use, and no history of either pregnancy or STDs) were 2.3 times more likely than the intervention group to be diagnosed with an STD (OR=2.3, CI-2.3-3.9).

Conclusions: The high prevalence of sexual risk behaviors and STDs in this national, non-clinical, sample of young women suggest the need for ongoing STD prevention programs for young women post high school. Moreover, the findings of this randomized controlled trial indicate that multi-session, cognitive-behavioral interventions are feasible and effective strategies for preventing STDs in at risk women. Finally, this study represents the first and largest successful intervention of its kind.

Journal of Adolescent Health, 32(2):128, 2003

PREVALENCE OF BACTERIAL VAGINOSIS (BV) BY NUGENT'S CRITERIA IN A NON-CLINIC NATIONAL SAMPLE OF YOUNG WOMEN ENTERING THE MILITARY: RELATIONSHIPS WITH SEXUAL EXPERIENCE, VAGINAL SYMPTOMS AND SIGNS

Sophia Yen, M.D., Mary-Ann Shafer, M.D., Jeanne Moncada, M.S., Cherrie B. Boyer, Ph.D., Dept. of Pediatrics, Dept of Laboratory Medicine, University of California, San Francisco, CA.

Purpose: To determine and compare the prevalence of bacterial vaginosis (BV) by Nugent's Gram stain criteria in a racially and ethnically diverse, non-clinic young adult female sample between sexually-experienced and sexually-inexperienced young women, and to determine the clinical correlates of a BV diagnosis.

Methods: A cross-sectional study of a voluntary sample of 2157 young women from throughout the United States entering military recruit training was conducted as a part of a larger behavioral-cognitive study designed to prevent STDs and unintended pregnancy. Self-administered vaginal swabs were applied to a glass slide for Gram stain. A positive test for BV was defined by a Nugent score ≥ 7.

Results: Participants with complete data included in the analysis were 1938 women with a mean age of 19.1 years, a diverse racial/ethnic profile (56% Caucasian, 20% Hispanic, 16% African American, 3% Asian/Pacific Islander, 2% Native American, 2% Other/Mixed); 86% were sexually experienced. *Clinical:* At examination, 20% self-reported vaginal discharge and 7% self- reported vaginal odor, while clinicians noted vaginal discharge in 5%. *Laboratory:* 27% were BV (+) by Nugent's criteria (28% in those sexually-experienced, 18% in not sexually-experienced. In addition, BV by Gram stain was positively related to: a history of sexual activity, self-report of vaginal discharge, self-report of vaginal odor and current diagnosis of *C. trachomatis* (all $p<.003$). BV diagnosis was inversely related to hormonal contraceptive use ($p=.013$) . There was no significant difference in the proportion of those women with and without BV with respect to: self-report of vaginal itching, clinician detection of vaginal discharge, prior history of STD, >1 partner in the past three months and current diagnosis of *N. gonorrhoeae* or *T. vaginalis*.

Conclusion: BV occurs commonly among this sample of young women entering military recruit training in both the sexually-experienced and inexperienced. Young women's self-report of vaginal discharge and odor were highly correlated with a diagnosis of BV. Thus, clinicians should evaluate both sexually-experienced and inexperienced young women complaining of vaginal discharge and odor for BV. Further studies are needed to elucidate the relationship of BV with *C. trachomatis* and hormonal contraceptives.

APPENDIX 3.h.
Ottawa, Canada, 2003

Preventing STDs And Unplanned Pregnancy in a National, Non-Clinical Sample Of Young Women: A Cognitive-Behavioral, Group, Randomized Controlled Intervention Trial For Military Recruits

Boyer CB_1, Shafer MA_1, Schachter J_1, Shaffer RA_2, Pollack L_1, Chang Y_1, Brodine $S_{2,3}$
$_1$University of California, San Francisco, San Francisco, CA, $_2$Navel Health Research Center and $_3$ San Diego State University, San Diego, CA, USA

Objective: To evaluate the effectiveness of a cognitive-behavioral intervention to prevent sexually transmitted diseases (STDs) and unplanned pregnancies (UPs) in young women from all 50 US states and territories enrolled in military recruit training between June 1999 and June 2000.

Methods: 2157 (94%) women were randomly assigned by platoons to experimental and control interventions. Participants completed a self-administered questionnaire and were screened for pregnancy, *C. trachomatis*, *N. gonorrhoeae*, and *T. vaginalis* at baseline, 2-4 weeks, and 9-12 months post- intervention. Guided by the Information, Motivation, and Behavioral Skills Model, the experimental intervention consisted of four, two-hour interactive and didactic small-group sessions that focused on reproductive anatomy, contraceptive methods, alcohol/other substances, peer norms, self-efficacy, and communication/problem-solving skills. The control intervention was conducted in a similar format and focused on promoting healthier food choices and preventing physical training injuries. Logistic regression analyses regressed post-intervention STDs, UP, and sexual behaviors on intervention group, pre-intervention sexual history ('not sexually experienced', 'safe-no history', 'unsafe-no history', 'STD/pregnancy history'), and latency clustered by platoon.

Results: The participants were primarily young, (mean age=19.2 years), single (92%), diverse (44% non-Caucasian), and sexually experienced (85%). At baseline, 14% were diagnosed with STDs (11% *C. trachomatis*, 2%, *N. gonorrhoeae*, 2% *T. vaginalis*). Participants in the control intervention were significantly more likely to have an STD or UP post-intervention (AOR =1.41, CI =1.01-1.98). Significant sub-group differences were also found; control intervention participants who were 'unsafe' were more likely to acquire an STD (AOR =3.24, CI=1.74 - 6.03) post-intervention. Additionally, control intervention participants who were 'not sexually experienced' were more likely to have multiple sexual partners (AOR=1.87, CI=1.01-3.47) and casual sexual partners (AOR=2.05, CI=1.09 - 4.08) post-intervention.

Conclusions: This randomized controlled trial indicates that small-group, multiple-session, cognitive-behavioral interventions are effective strategies for preventing STDs, UPs, and reducing sexual risk in young, at-risk women.

PREDICTING ACQUISITION OF C.TRACHOMATIS, N.GONORRHOEAE, AND T.VAGINALIS IN A NON-CLINICAL NATIONAL SAMPLE OF YOUNG MILITARY WOMEN DURING THEIR FIRST YEAR OF SERVICE

Shafer MA_1, Boyer CB_1, Schachter J_1, Moncada J_1, Pollack LM_1, Chang Y_1, Shaffer RA_2, Brodine $S_{2,3}$
$_1$University of California, San Francisco, San Francisco, CA, $_2$Navel Health Research Center and
$_3$ San Diego State University, San Diego, CA, USA

Objective: To determine STD acquisition rates and evaluate sociodemographic, behavioral, and reproductive health factors predicting *C. trachomatis* (CT), *N. gonorrhoeae* (GC), and *T. vaginalis* (TV) acquisition in a non-clinical, national sample of young women during their first year of military service.
Methods: During recruit training 2157 (94%) women volunteered to participate in an intervention to decrease STD acquisition and unplanned pregnancy (UP). At baseline (T1), all participants completed a self-administered questionnaire and were screened for CT, GC (urine, self-collected vaginal swabs by LCx^R) and TV (Trich In-$Pouch^R$). All positives were treated. Participants were re-screened by questionnaire and STD tests at 3 months-T2 (including two weeks leave) and 9-12 months (T3) after baseline. This study represents analyses of STD acquisition between T2-T3.
Results: Participants were young, (mean age=19.2 years), single (92%), diverse (44% non-Caucasian), and sexually experienced (85%). At follow-up, 754 women had complete data on both assessments (>80% of anticipated follow-ups); 18% acquired an STD (17% CT, 2% GC, .2% TV), and 13% had an unplanned pregnancy. Sociodemographic, behavioral, and reproductive health factors that were significant ($p<.10$) at the bivariate level were entered into a backward stepwise logistic regression model while adjusting for intervention group participation and time between T1 and T3 assessments. Race/ethnicity [African American vs. Caucasian (AOR=1.71, 95% CI 1.01-2.95); Native American vs. Caucasian=7.04, 95% CI=2.78-18.53], number of partners [$\geq$3 vs. $\leq$1 (AOR= 2.51, 95% CI=1.42-4.42)], perceived sexual partner(s) had an STD [yes/possible vs. no (AOR=3.08, 95% CI=1.99-4.78)], pregnancy since recruit training [yes vs. no (AOR=1.80, 95% CI=1.06-3.06)] were associated with acquisition of STDs during the women's first year of military service. The Hosmer-Lemshow Goodness of Fit Test was p=0.40.
Conclusions: This study highlights the need for STD prevention including routine universal screening for STDs especially chlamydia among young military women during their first year of service.

Appendix 4

Presentations

a. Boyer CB, Shafer MA. Preventing STDs and Unplanned Pregnancies: A Cognitive-Behavioral Intervention for Young Women Entering the Military. *Journal of Adolescent Health*, 32(2):129, 2003.

b. Shafer MA, Boyer CB, Schachter J, Moncada J, Pollack LM, Chang Y, Shaffer RA. Predicting Acquisition of *C. Trachomatis*, *N. Gonorrhoeae*, and *T. Vaginalis* in a Non-Clinical National Sample of Young Military Women During Their First Year of Service. Presented at the 2003 ISSTDR Congress, Ottawa, Canada, July 27-30, 2003.

Appendix 4.a.

Boyer CB, Shafer MA. Preventing STDs and Unplanned Pregnancies: A Cognitive-Behavioral Intervention for Young Women Entering the Military. *Journal of Adolescent Health*, 32(2):129, 2003.

Preventing STDS and Unplanned Pregnancies: A Cognitive-Behavioral Intervention for Young Women Entering the U.S. Military

Cherrie B. Boyer, PhD
Mary-Ann Shafer, MD

Department of Pediatrics,
Division of Adolescent Medicine
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Fort Detrick, MD

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Y. Jason Chang, MS, CAPS, UCSF

Background

- Sexually experienced women, ages 15-24 years, have the highest rates of chlamydia and gonorrhea.
- These infections pose serious health concerns because of their association with pelvic inflammatory disease, tubal infertility, ectopic pregnancy, and HIV.
- The risk of STDs is the result of complex interrelationships among sociodemographic and behavioral risk factors.

Background

- Little is known about the risk and prevention of STDs and unplanned pregnancies in healthy, non-clinic samples of women.
- Military training, with defined opportunities for risk, is an ideal setting for evaluating prevention interventions in young women.

Until now, the military has taught only two methods of contraception...

Primary Goal

To prevent unplanned pregnancies and STDs in women entering recruit training for the U.S. Marine Corps.

Methods

- All women (N= 2288) enrolled in recruit training at the United States Marine Corps Recruiting Depot in Parris Island SC, between June 1999 and June 2000 were recruited to the study.
- Military personnel were not present during recruitment.
- 2157 (94%) women volunteered to participate in a cognitive-behavioral, skills-building intervention to prevent unplanned pregnancies and STDs or a nutrition and fitness intervention.

Methods (continued)

- Assignment to the interventions was randomized by platoons.
- The participants completed self-administered questionnaires and were screened for *C. trachomatis*, *N. gonorrhoeae*, and *T. vaginalis* at three assessments.

Study Design

Baseline T1	Initial Follow – up T2 2- 4 weeks	Second Follow-up T3 9-12 months
Questionnaire STD Screen Interventions "FOCUS" "Fitness for Life"	Questionnaire STD/Pregnancy Screen	Questionnaire STD/Pregnancy Screen

"FOCUS" Curriculum Goals
Experimental Intervention

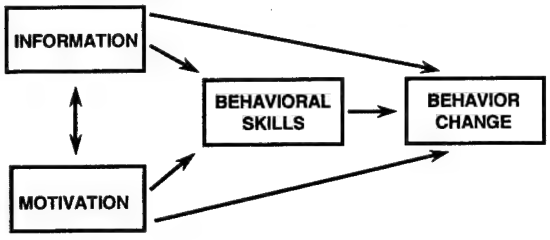
- Educate about the risk and impact of unplanned pregnancies, STDs and HIV.
- Provide factual information on effective methods of contraception and STD prevention.
- Describe the basics of a GYN exam and female reproductive anatomy.

"FOCUS" Curriculum Goals (continued)

- Build communication and decision-making skills regarding sexual behaviors and use of contraception.
- Provide information about the effects of alcohol use on sexual risk behaviors.

"FOCUS" Theoretical Framework

Information-Motivation-Behavioral Skills Model



Fisher & Fisher, 1992; 1996

"FOCUS" Strategy

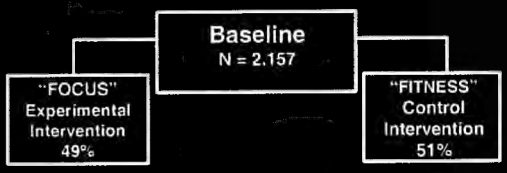
Approach

- Didactic Slides
- Interactive Group Exercises
- Military-Specific Videos

Format

- Small Groups (20-25)
- 4, Two-hour Sessions

Group Assignment



Baseline Characteristics

Age	
17-18	54%
19-20	31%
≥ 21	15%
Race/Ethnicity	
Caucasian	56%
Latina	20%
African American	16%
Asian/PI/Native American	8%

Baseline Characteristics

Marital Status	
Married	8%
Single	92%
Geographical Location of Residence	
Urban	78%
Rural	22%

Baseline Behavioral Risk

Sexual Partners	
1	18%
≥ 2	82%
Casual Partners	
≥1	65%
Frequency of Birth Control	
Never/Sometimes	33%
Usually/Always	67%
Condom Use	
< 100%	78%

Baseline STD Prevalence

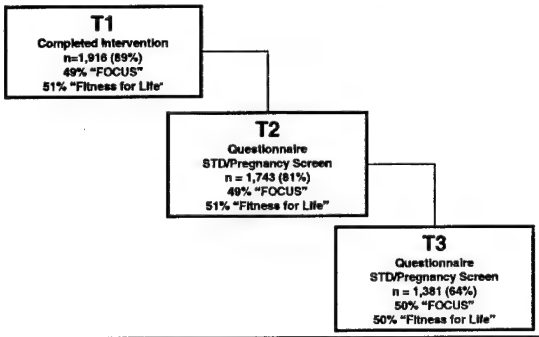
Any Positive	**14%**
C. trachomatis*	**11%**
N. gonorrhoeae*	**2%**
T. vaginalis **	**2%**

* by LCx^R
** by Trich-In-Pouch^R (self-swab)

Baseline Behavioral Risk Categories

NSE (Safe) (15.6%)	Not sexually experienced
No HX (Safe) (20.4%)	Sexually experienced but no hx pregnancy/STDs ~AND~ 1 partner and 100% condom use
No Hx (Unsafe) (31.7%)	Sexually experienced but no hx pregnancy/STDs ~AND~ ≥2 sex partners or < 100% condom use
HX (32.3%)	Had hx pregnancy/STDs

Assessments



Post Intervention STD Acquisition

Any Positive	**8%**
C. trachomatis*	**7%**
N. gonorrhoeae*	**1%**
T. vaginalis **	**.5%**

* by LCx^R
** by Trich-In-Pouch^R (self-swab)

Post Intervention Behavioral Risk

Unplanned Pregnancy	**4%**
Multiple Sexual Partners	**57%**
Casual Sexual Partners	**43%**

Effect of Intervention
Unplanned Pregnancy or STD Acquisition

% Positive		
Fitness	**Focus**	**Odds Ratio#**
26%	**21%**	**1.41***

*p< 0.05
#Adjusted for history of STDs, pregnancy and risk behaviors, latency, and clustering effects by platoon

Effect of Intervention
STD Acquisition

Sexual History	% Positive Fitness	% Positive Focus	Odds Ratio#
NSE	16%	10%	1.68
No Hx (Safe)	11%	12%	0.60
No Hx (Unsafe)	24%	9%	3.24***
Hx (STDs/Pregnancy)	22%	24%	0.96

*** p< 0.001
#Adjusted for latency and clustering effects by platoon

Effect of Intervention
Multiple Sexual Partners

Sexual History	% Positive Fitness	% Positive Focus	Odds Ratio#
NSE	35%	25%	1.87*
No Hx (Safe)	60%	55%	1.45
No Hx (Unsafe)	60%	70%	0.70
Hx (STDs/Pregnancy)	56%	60%	0.93

*p< 0.05
#Adjusted for group, latency, and clustering effects by platoon

Effect of Intervention
Casual Sexual Partners

Sexual History	% Positive Fitness	% Positive Focus	Odds Ratio#
NSE	31%	18%	2.05*
No Hx (Safe)	42%	40%	1.11
No Hx (Unsafe)	46%	55%	0.69
Hx (STDs/Pregnancy)	43%	44%	0.93

*p< 0.05
#Adjusted for group, latency and clustering effects by platoon

Discussion

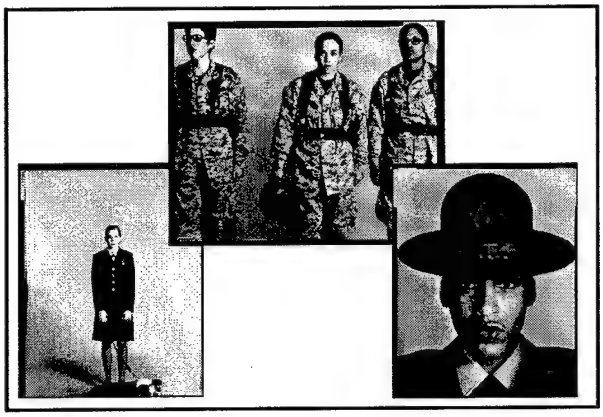
- Overall, women participating in the experimental intervention were less likely to have an unplanned pregnancy or an STD.
- As expected, the intervention's effect differed by levels of risk.
- Our experimental intervention had the most salient impact on reducing STDs in women who, at baseline, had multiple sexual partners or used condoms inconsistently.

Discussion

- Women participating in the experimental intervention, who were not sexually experienced at baseline, were less likely to engage in sex with multiple or casual partners when they initiated sex.
- These findings suggest that future interventions may need to consider other factors in order to have an impact on women in other risk categories.
- Future intervention trials may need to be greater than 8 hours or may need to more intensively emphasize components of the IMB model.

Conclusions

- The high prevalence of sexual risk and STDs in this national, non-clinical sample of young women suggests the need for ongoing reproductive health interventions for young women post high school.
- The findings of this randomized controlled trial indicate that cognitive-behavioral skills-building interventions are both feasible and effective strategies to reduce behavioral risk and prevent STDs and unplanned pregnancies in young at risk women.



Appendix 4.b.

Shafer MA, Boyer CB, Schachter J, Moncada J, Pollack LM, Chang Y, Shaffer RA. Predicting Acquisition of *C. Trachomatis*, *N. Gonorrhoeae*, and *T. Vaginalis* in a Non-Clinical National Sample of Young Military Women During Their First Year of Service. Presented at the 2003 ISSTDR Congress, Ottawa, Canada, July 27-30, 2003.

Predicting Acquisition of *C. trachomatis, N. gonorrhoeae,* and *T. vaginalis* in a Non-clinical National Sample of Young Military Women During Their First Year of Service

Determining STD Acquisition Rates: Challenges of Defining Positives and Selecting Time Frames

Collaborators

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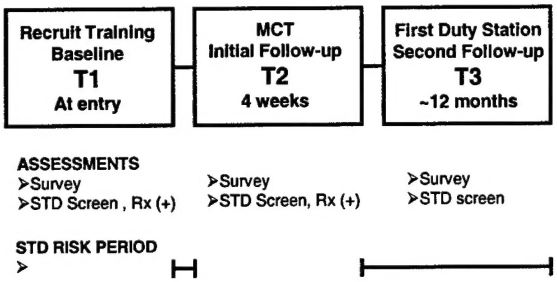
Background

- Highest STD rates among 15-24 yo females
- Undetected, untreated→PID, infertility
- Little information on STD acquisition using multiple consecutive time frames
- Challenges in determining acquisition rates:
  - ➢ defining the population
  - ➢ defining a positive STD
  - ➢ selecting appropriate time frames

Objectives

- To determine the acquisition rates of CT, GC and TV among healthy military women during the first year of service
- To compare acquisition rates by differing definitions of a positive:
  - ➢Include only results from STD tests
  - ➢Include STD tests + interim self-report survey
  - ➢Use different timeframes

Study Design



METHODS

Subjects

- All women (N=2288) enrolled in recruit training at the US Marine Corps Recruit Depot: June 1999-June 2000
- 2157 (94%) Ss volunteered to participate in a cognitive-behavioral-skills building intervention (see Boyer et al, ISSTDR Poster)

Clinical Specimens*

- FVU
  - ➢CT, GC by LCx™
- Vaginal swabs (self-collected)
  - ➢CT, GC by LCx™
  - ➢TV by Trich In-Pouch™
- Endocervical swab
  - ➢CT, GC by LCx™

*Positive = Any positive on one or more specimen

Laboratory Processing

- FVU:CT, GC by LCx™
  - ➢Frozen, shipped overnight to UCSF lab
- Vaginal swabs (self-collected)
  - ➢CT, GC by LCx™ (same as FVU)
  - ➢TV by Trich In-Pouch™ (on-site staff)
- Endocervical swab: CT, GC by LCx™
  - ➢Only done at baseline T1
  - ➢Cold chain to local Navy lab

Self-administered Surveys

- Sociodemographic information
- Reproductive health history, STDs
- Risk behavior history (e.g., sexual behaviors, alcohol)

RESULTS

Baseline Characteristics
N=2157

Baseline Demographics

Age (17-20)	85%
Race/Ethnicity	
Caucasian	56%
Latina	20%
African American	6%
Asian/PI/Native Am./Other	8%
Marital Status (Single)	92%
Location of Residence (Urban)	79%

Baseline Sexual Behaviors

- Sexual Partners (≥2 ever) 82%
- Casual Partners (≥1 ever) 65%
- Birth Control (Usual/Always) 67%
- Condom Use (< 100%) 78%

Baseline STD Prevalence

Any (+)	14%
*C. trachomatis**	11%
*N. gonorrhoeae**	2%
*T. vaginalis***	2%

* by LCx^R
** by Trich-In-Pouch^R (self-swab)

DETERMINING ACQUISITION RATES

Defining the Population to Determine Acquisition Rates

Goal was to include only women who:

- Sexually active
- Not exposed to STD intervention
- Complete biological data T2 & T3 and complete survey data at T3

Determining Target Population

Consented at T1 — N=2157

⇩

Sexually active since T1 — N=1192

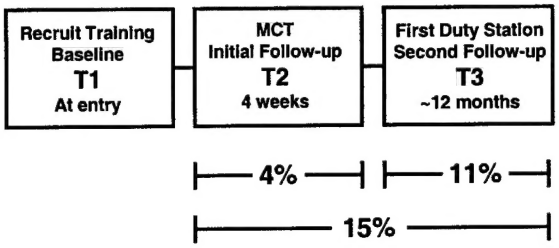
⇩

Complete T2 & T3 bio data & complete survey data T3 — N=648

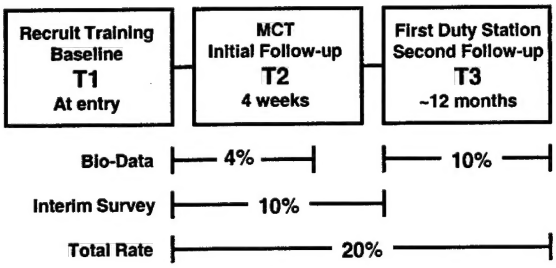
⇩

Complete T2 &T3 bio and survey data & no intervention exposure — N=332

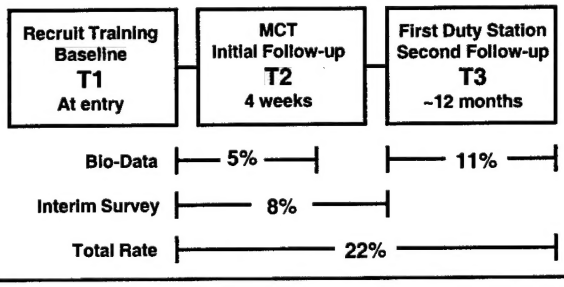
STD Acquisition Rate by Assessment Period



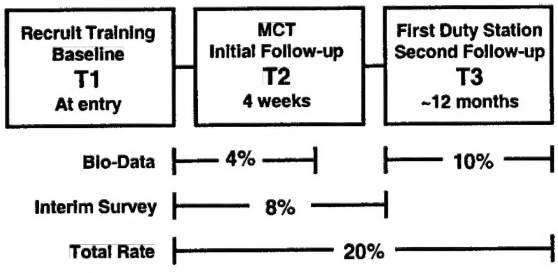
STD Acquisition Rate by Assessment Period (N=648)



STD Acquisition Rate by Assessment Period for Control Group Only (N=332)



C. trachomatis Acquisition Rate by Assessment Period



STD Acquisition Rate by Assessment Period

	Total	STDs No Intervent	CT No Intervent
N	648	332	332
T2 (Bio)	4%	5%	4%
T3 (Bio)	10%	11%	10%
T2+T3 (Bio)	13%	15%	13%
Interim Survey	10%	9%	8%
T2+Intr.+T3	20%	22%	20%

CONCLUSIONS

- STDs are common among women recruits at T1 (14%) with CT responsible for most infections
- STD acquisition rates at T2 (4%), T3 (11%) & by self-report (7%) were high
- STD acquisition rates may vary by definition of the eligible population, number of data points, and numbers & types of specimens and tests done

IMPLICATIONS

- Universal screening for STDs, esp. CT, must be done for women entering the military
- Following national guidelines, annual screening for CT in this young population is needed, and more frequent screening among high risk women may be indicated

IMPLICATIONS

- Reported acquisition rates which use one or two data points over time and use only one specimen may underestimate the actual acquisition rate of common STDS, especially CT